UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *EX REL.* SUSAN VIERCZHALEK, M.D., STATE OF CALIFORNIA, STATE OF DELAWARE, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF ILLINOIS, STATE OF INDIANA, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, and STATE OF WISCONSIN. Plaintiffs, - v. - MEDIMMUNE, INC., TRINITY HOMECARE, LLC, and OPTION CARE, INC., Defendants.	09 Civ. 3919 (RJS)

RELATOR'S AMENDED COMPLAINT

On behalf of the United States of America, the states of California, Delaware, Florida, Georgia, Illinois, Indiana, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, and the Commonwealths of Massachusetts, and Virginia (collectively, the "States"), Plaintiff and *qui tam* Relator, Susan Vierczhalek, M.D., by and through her attorneys, Lowey Dannenberg, P.C., file this *qui tam* amended complaint (the "Complaint") against defendant MedImmune, Inc. ("MedImmune" or the "Company").

Plaintiff's allegations are derived from her personal knowledge that protected health information ("PHI") in hospital neonatal intensive care units ("NICUs") was misappropriated from NICU logbooks at Bellevue Health Center ("Bellevue") and other hospitals, in violation of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as alleged in Relator's initial complaint (Dkt. No. 1), and that this PHI was used to make calls to try to trigger new or additional dose prescriptions for Synagis. Relator's investigation also shows that this misconduct, as well as providing other things of value to specialty pharmacies and doctors, were company-wide practices.

By Stipulation and Order of Settlement, Dkt. No. 34, (the "July 9, 2015 Order"), Relator and the State of New York ("New York" or the "State") settled claims asserted against former defendants Trinity Home Care, LLC, and Option Care ("Option Care") (referred to together and collectively with parent Walgreens, Inc. as "Trinity").

Relator incorporates by reference the Complaint in Intervention dated March 31, 2017 in *State of New York v. MedImmune, Inc.*, 09-civ-3919 (RJS) (S.D.N.Y.) (Dkt. No. 49) (the "State Cmpt."), and the State's findings in the July 9, 2015 Order at ¶¶ (a) through (y), which are summarized herein.

I. INTRODUCTION

1. MedImmune is the manufacturer of the drug palivizumab, sold under the brand name "Synagis." Synagis is FDA approved for use in high-risk infants to lessen the severity of lower respiratory tract disease caused by respiratory syncytial virus ("RSV").

2. Synagis is not a vaccine and will neither prevent nor cure RSV. RSV is the responsible for 2%-3% of infant hospitalizations in their first 12-months, or 75,000 to 125,000 hospitalizations annually.

3. As recognized by the Federal Food and Drug Administration ("FDA") and the American Academy of Pediatrics, patients at high risk of RSV include infants with a history of premature birth (less than 35 weeks gestational age), significant congenital heart disease, or chronic lung disease.

4. Synagis is expensive. It is injected into the infant once a month during certain months of the year when RSV is reported, the so-called "RSV season."[1] The typical regimen of five doses of Synagis costs about $5,000-$6,000, or more. Synagis is by far MedImmune's most commercially successful prescription drug, accounting for the bulk of the Company's revenues in the U.S. and internationally.

5. This action concerns a nationwide scheme orchestrated by MedImmune to increase its revenues and profits by targeting the most fragile families -- low-income parents on Medicaid -- whose babies were born premature. Many of these infants had not been prescribed Synagis in the hospital or discharged with a prescription for Synagis for RSV. Nor were parents of NICU babies who were born in the summer months given prescriber instructions to obtain a Synagis prescription during the next applicable Synagis season (typically beginning October).

6. To identify these NICU babies, MedImunne sales representatives confirm that it was "imperative" to form relationships with the hospital staff that had access to the NICU logs and with the pediatric office staff because the patient data in the NICU logbooks and pediatric offices was "critical" to achieving sales goals at MedImmune. However, access to and/or use of that information for marketing purposes was prohibited under HIPAA.

7. To gain access to PHI, MedImmune would provide valuable services to hospitals

[1] As will be discussed in depth (*see* ¶¶333-37), RSV season is documented through data annually. While it varies, a typical season is November through March. This should trigger five doses starting in October as preemptive to the onset of RSV season.

and pediatricians. These services included (i) "helping the staff" track discharged babies that were likely candidates for Synagis; (ii) reviewing and completing required paper work such as referral forms and other documentation needed to prescribe Synagis; (iii) providing lunches to physicians and their staff; and (iv) providing binders and forms to the offices; and (v) paying neonatologists (particularly high prescribing doctors) for speaking about RSV and Synagis. This was all done ultimately, to obtain payment from Medicaid and State funded programs such as MediCal through the submission of false claims tainted by kickbacks.

8. MedImmune collaborated with specialty pharmacies that dispensed Synagis, including Trinity, Advanced Pharmacy and Respiratory Care Solutions ("APS"), Acro Pharmaceutical Services LLC ("Acro"), and Caremark Specialty Care (a CAREMARK subsidiary) (together "Caremark"), in order to track discharged babies either through parents or pediatricians. At least one former employee of MedImmune described MedImmune as the "workhorses" for Caremark, and viewed Caremark as a "colleague." As part of that relationship, MedImmune sales representatives were encouraged by senior management to routinely share baby information in an effort to track NICU babies and attain their sales goals.

9. MedImmune's regional managers (referred to in the State Cmpt. as "Medi Managers"), whose territories covered multiple States, were also well aware of and encouraged the sales force to (1) access federally-protected patient information to obtain leads and solicit parents, (2) assist the hospital and pediatricians and their staff with the completion of referral forms, (3) host RSV season kick-off lunches in doctors' offices and (4) provide the PHI from NICUs and doctors' offices to pharmacies as referrals to track NICU babies.

10. MedImmune used baby PHI to provide valuable leads or referrals to Trinity and others, while also providing valuable office services; lunches and sales rebates, in order to

increase Synagis sales and MedImmune's profits. MedImmune has conceded that its practices with Trinity were widely adhered to with specialty pharmacies generally. These practices resulted in increased revenues by boosting Synagis sales.

11. MedImmune's regional and senior managers knew these practices violated applicable healthcare laws, the Company's own policies and Corporate Integrity Agreements ("CIA") that Astrazeneca and its subsidiaries were bound to by settlements with the Federal government. Nonetheless, to achieve management's sales goals and projections salespeople were to do whatever it took to get PHI. A former Biotech Sales Specialist ("BSS"), who covered the Los Angeles, California territory ("BSS-CA3") during 2006-2011, said that MedImmune's "aggressive" sales goals were not attainable unless representatives followed these practices to identify and track NICU babies post-discharge. Former BSS-CA1, who covered that territory from 2004-2007, confirmed that the whole sales projection process at MedImmune was based on sales representatives obtaining PHI. BSS's presented the hospital NICU baby numbers to their managers.

12. When informed by one of his New York sales representatives that "[n]ow I do 100% of the tracking and the info. flows from the NICU," the regional manager (designated by the State as "Medi Manager 1") responded that: "This is absolutely terrific work!!! … Keep this same level of intensity throughout the entire season and success will be yours!" State Cmpt., ¶¶161-62.

13. The regional manager's superior (designated "Medi Manager 5"), who was copied on the "NICU Update," also praised the sales representative's initiative, acknowledging "that this work takes extraordinary effort and finesse." *Id.*, ¶163. Medi Manager 5 further responded to the sales representative: "Thanks for the perspective. Congratulations and great job in taking

control of the process this summer." *Id.*

14. In another exchange, Medi Manager 1 thanked his sales representative "for a very productive day" in which he "performed some true hospital salesmanship." *Id.*, ¶164. Medi Manager 1 recounted that the sales representative's "NICU protocol produced another 21 babies identified for Synagis administration in the last (3 weeks) 126 to date." *Id.*

15. This misconduct was throughout MedImmune. BSS-CA1 (2004-2007), BSS-CA2 (2011-2012), and BSS-CA3,[2] all confirmed that gaining access to NICU logbooks and pediatrician records were critical to the sales process at MedImmune. The NICU staff at St. Francis Medical Center in Lynwood, California and Cedars-Sinai allowed MedImmune's sales representative access to the NICU logbooks and/or provided lists of babies who were being discharged, so that MedImmune could track babies post-discharge.

16. MM-PA/NJ, an Area Business Manager from 2007 to 2012 for Pennsylvania, and for a short period of time, part of New Jersey, supervised two clinical marketing managers ("CMMs) and 10 biotech sales specialists. His sales staff routinely obtained patient data for tracking purposes from hospitals such Children's Hospital of Philadelphia, UPMC Pittsburg, Pinnacle Hospital, Lancaster General, St. Joseph Hospital, and St. Christopher's Hospital for Children. He and his people worked alongside pediatricians and their staff, and exhorted them with the marketing matra to be Synagis "champion."

17. Further, at large Philadelphia area "teaching hospitals" such as Children's Hospital, Lancaster General, and St. Christopher's. CMMs were given access to discharge forms for NICU babies, which included the patients' names, dates of births, gestational ages, insurance coverage details, the names of the pediatricians to whom the babies were discharged, and any

notes that the hospital staff provided. The CMMs faxed these discharge forms to the biotech sales specialists, who then tracked the babies in conjunction with staff from the pediatricians' offices.

18. BSS-CA1 and other sales representatives throughout the Company reported a uniform practice developed by seasoned professionals of maintaining patient information in "Synagis binders." MedImmune's sales people and managers shared this information often with specialty pharmacies such as APS, the largest provider of Synagis to the California Medi-Cal program, and Caremark, in order to track post-NICU babies that were candidates for Synagis.

19. "BSS-CA1 hit all the pediatricians' offices during the summer" with her binders, asking, "who is going to be the Synagis champion?" BSS-CA1 enlisted office staff to help identify and track potential Synagis patients. These staff members filled in babies' names and dates of birth in binders that BSS-CA1 purchased and maintained at the pediatrician's office. BBS-CA1 had full access to that data and used it to facilitate the tracking process to follow-up on tracking the NICU babies for Synagis dosing. This way BSS-CA1 "took the work off the hands" of the doctors' office staff.

20. BBS-CA3 likewise purchased binders which were maintained at pediatrician offices in southern Los Angeles, including Pico Rivera and Whittier, CA. BBS-CA3 and other biotech sales specialists used the binders to review the list of patients seen by each pediatrician and determine where the patients were in the process of the Synagis regimen. The biotech sales specialists also provided service of value to doctors by using the binders to "help organize" the treatment of Synagis patients, including tracking appointments, "following through with the pharmacy" and completing referral forms.

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2 The two-letter suffix after each MedImmune salespersons' identification indicates the state(s) in which they sold

21. BSS-CA2 confirmed that MedImmune's sales force continued to access hospital NICU logs up during his tenure in the southern California territory in 2011-2012. It was his normal practice to look at NICU logs in hospitals such as Long Beach Memorial and Fountain Valley Regional in order to (1) track patients to ensure that they received future shots of Synagis, (2) provide hospitals assistance in completing referral forms needed to obtain prescriptions for Synagis, and (3) follow-up with pediatricians who treated these babies post-discharge. Both of these hospitals had a high number of low income patients, often covered by Medicaid, or MediCal. Many of the low income mothers gave birth prematurely, and their infants were placed in the NICU.

22. Senior managers knew and encouraged sales representatives to assist with the completion of referral forms. BSS-CA3 reported that this was a "common practice" and could not think of another in her territory who did not allow this activity. BSS-CA3's sales managers encouraged her to lend assistance to pediatricians and "do whatever she needed to" in order to attain sales goals.

23. MM-PA/NJ's said MedImmune sales representatives typically spent an hour or longer, on average, during each visit to the doctors on which they called. This time was spent reviewing charts, coaching staff and doctors on ways to get babies qualified, and putting "Synagis stickers" on charts of babies who the MedImmune representatives believed could be eligible for Synagis. Synagis binders maintained in the doctors' offices were regularly referred to as "tracking binders." The MedImmune sales representatives had access to these binders, which included the number of babies dosed with Synagis by the doctors' office year over year, the current dosing schedule for the babies seen in that office and all of the patients' identifying

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Synagis.

information on the discharge forms, and type of insurance the patients carried.

24. MedImmune created a field reimbursement manager position in approximately 2009. The field reimbursement managers were not tied to sales and did not have sales goals. They were tasked with assisting physicians and their staff with the completion of referral forms.

25. Defendant's lunch, referral-and-assistance kickback scheme was highly successful. MedImmune touted the fact that almost one-half of the parents that the Company made aware of Synagis ended up using the Synagis drug treatment for their infant children. The State of New York data reflects a similar outcome with more than 600 out of a total of 1,250 confirmed baby leads from the misappropriated PHI, resulting in Synagis treatments, paid for through Medicaid claims tainted by kickbacks. The State Cmpt., attaches as Exhibits C-1 and C-2, lists identifying approximately 600 babies and, in many cases, the hospital NICU from which MedImmune improperly obtained leads and referrals that resulted in Trinity submitting claims for Synagis paid by Medicaid. The State calculated that from those baby lists alone MedImmune benefited by $7.3 million by causing the submission of false claims that were paid by the State. State Compt. ¶15.

26. Similarly, MM-PA/NJ reported that he worked closely with a specialty pharmacy based in Sharon Hill, Pennsylvania, that fulfilled prescriptions of Synagis for Medicaid and private insurers. MM-PA/NJ met monthly with representatives from this pharmacy to review how many doses were being sent to particular doctors, and in the process, shared PHI with the pharmacy representatives.

27. MedImmune has conceded that it "coordinated among hospitals and specialty pharmacies like Trinity" and openly acknowledged that "MedImmune, Trinity and others worked to help identity patients who were potentially at risk for RSV, and therefore might benefit from

Synagis." *See* Letter dated June 5, 2017 to Hon. Richard J. Sullivan, Dkt. 60. As described in detail herein, MedImmune accomplished its sales goals through improper means – obtaining access to PHI and using those leads, along with administrative assistance; lunches, speaker fees, office materials and other valuable services, as kickbacks to: doctors; Trinity; other specialty pharmacies and healthcare providers.

28. Indeed, MedImmune's Associate Director of Sales, Training, and Development and thereafter, Compliance Director of AstraZeneca North America, from 2007 through 2011 and beyond ("Medi/AtraZeneca Compliance Director"), admitted that if MedImmune employees provided pharmacies with names of babies that could lead to the pharmacy obtaining prescriptions of Synagis for those babies, this would be conduct that could be considered added value or a kickback. State Cmpt., ¶14.

29. Relator raised formal complaints concerning NICU access, misappropriation of PHI to generate prescription and the misappropriation of medical credentials to write prescriptions. An internal investigation ensued which led to Bellevue barring Synagis salespeople from its NICU in March 2009. A few months later, MedImmune was barred from Kings County Brooklyn Hospital's NICU. Without access to the NICU, MedImmune was no longer able to access leads or to directly contact parents of babies discharged from the NICU. Nor could it forward their information to Trinity or other pharmacies for follow-up. *Id.*, ¶151-54. MMPA/NJ reports that in 2009 the Company changed what they called their practices, but not the practices themselves.

30. Relator reported to counsel and to the NYAG and USAO continuing concerns about calls that came into the clinic every year where residents were asked to sign off on prescriptions for Synagis for babies by name and with the patient's medical history. Some of

these calls were for new prescriptions, some were for "April doses" due to purported widespread and high risk of RSV in the area. These prescriptions were unwarranted in the medical judgment of Relator and the resident doctors receiving these calls. Some of these calls for extra doses were tracked and documented on patient files. No database supports rampant RSV at the time of those calls.

31. By December 2010, MedImmune learned that a New York investigation was underway. The Company undertook a company-wide termination of its clinical marketing manager ("CMM") – specialized hospital salesperson position. *Id.*, ¶155. In April 2011, MedImmune's compliance department directed its employees to destroy any paper and electronically saved PHI in their possession by: shredding it, depositing it in confidential waste bins, or by completely electronically deleting it. *Id.*

32. MedImmune's directive violated its obligations to retain documents required under CIAs between AstraZeneca and the Federal government entered into in June 2003 and April 2010. The CIAs required that AstraZeneca and its subsidiaries "maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with [the] CIA for six years (or longer if other required by law) …"

33. MedImmune's document destruction directive also violated the Company's Code of Conduct, which incorporated the document retention obligations from the CIAs.

34. Relator seeks to recover nationwide damages and civil penalties on behalf of the United States of America and for the States as alleged arising from misconduct by MedImmune, including: (a) knowingly causing and conspiring to be presented to the United States government (the "Government") a false or fraudulent claim for payment or approval; and/or (b) knowingly causing and conspiring to be made or used false records or statements to get a false or fraudulent

claim paid or approved by the Government, in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq*., as amended (the "False Claims Act" or "FCA") and the States' FCA analogs (the "State Statutues").

35. Relator specifically alleged false claims presented with the use of PHI and unauthorized use of her medical license; she reported other such conduct and the State has documented prescriptions from the false and fraudulent claims that MedImmune caused Trinity to present to Medicaid in New York. The improper sales and kickback practices were Companywide, and resulted in the submission of material false claims that, upon information and belief, collectively caused the submission for payment of false claims by the States and Federal Medicaid programs.

36. Had the Federal and State payors known that Synagis Medicaid claims resulted from misappropriated PHI that was used as sales leads and that MedImmune provided valuable services and other things of value to hospitals and doctors' offices and as part of illegal kickback arrangements, the Federal and State Medicaid payors would not have reimbursed Trinity, APS, Acro, Caremark and other pharmacies and healthcare providers for those claims.

37. Relator seeks to recover treble damages and civil penalties on behalf of the Federal Government and States arising from Defendants' misconduct, including violations of the States' respective FCA and anti-kickback statutes. The false or fraudulent claims, statements, and records at issue involve payments made by health insurance programs funded by these Federal and state governments, including Medicaid.

II. JURISDICTION AND VENUE

38. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, because this action involves a federal question, and 31 U.S.C. § 3732, which

confers subject matter jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3729 *et seq.*

39. This Court has personal jurisdiction over Defendants because they regularly transact business within the Southern District of New York.

40. This Court has supplemental jurisdiction over the *qui tam* Relator's state law claims pursuant to 28 U.S.C. § 1367, as those claims are so related to the federal claims that they form part of the same case and controversy under Article III of the United States Constitution. This Court also has jurisdiction over the Relator's state law claims pursuant to 31 U.S.C. § 3732(b) as these claims arise from the same transactions and occurrences as the federal claim.

41. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) & (c) as Defendant transacts business in this District.

42. The Relator is the original source of the discovery of the wrongdoing alleged herein.

43. As required by the FCA, 31 U.S.C. § 3730(a)(2), the Relator has provided to the Attorney General of the United States and to the United States Attorney for the Southern District of New York and appropriate State regulators, prior to the filing of this Complaint, a statement of all material evidence and information related to the Complaint. Because the statement includes attorney-client communications and work product of Relator's attorneys, and is submitted to the Attorneys General of the various States and to the United States Attorney in their capacity as potential co-counsel in the litigation, the Relator understands this supplemental disclosure to be confidential.

III. THE PARTIES

A. Relator

44. Plaintiff-Relator Susan Vierczhalek, M.D. (hereinafter, "Dr. Vierczhalek" or "Relator") is a resident of New York. Dr. Vierczhalek is a licensed pediatrician and attending physician at Bellevue Hospital Center in New York City ("Bellevue"). She also serves as faculty member at the New York School of Medicine where she is an Associate Professor of Clinical Pediatrics.

45. Dr. Vierczhalek is the Medical Director of the Bellevue Newborn Nursery, Medical Director of the Bellevue Breastfeeding Program and Co-Director of Bellevue's premature infant follow-up clinic (known at the "PINK Clinic"). This program provides comprehensive care to medically fragile infants, including those born extremely premature, after they are discharged from Bellevue's NICU. In this capacity, Dr. Vierczhalek provides outpatient pediatric care to high-risk infants; coordinates an interdisciplinary team which includes nurses, social workers, child life specialists and nutritionists; and teaches residents and medical students about caring for medically complex infants.

46. Because Relator and her colleagues ran the PINK Clinic, Relator was recognized as a Synagis doctor.

47. Dr. Vierczhalek routinely diagnoses and treats infant patients who were born prematurely and were discharged from Bellevue's NICU. Relator's team follows high-risk babies who meet certain criteria.

48. Relator brings this action for violations of the FCA and the State Statutes as set forth herein, upon personal knowledge as to herself, including the investigation of her counsel, and her own acts, and upon information and belief as to all other matters, on behalf of herself, the United States of America, and the State Plaintiffs.

B. Defendant

49. Defendant MedImmune is an American drug manufacturer that is a wholly-owned subsidiary of AstraZeneca PLC "(AstraZeneca"), an international biopharmaceutical company headquartered in London, England. MedImmune is organized under the laws of Delaware with its principal place of business located at One Immune Way, Gaithersburg, Maryland 20878. MedImmune is a leading biotechnology company and the manufacturer and distributor of the drug Synagis, which was sold throughout the United States.

50. Throughout the relevant period, Synagis sales (which for several years exceeded $1 billion) accounted for the vast bulk of MedImmune's total annual sales.

C. Settling Defendants

51. Former defendant Trinity Homecare LLC is a limited liability company organized under the laws of New Jersey with its principal place of business located at 114-02 15th Avenue, College Point, New York 11356. Trinity is a wholly owned subsidiary of OptionCare, Inc. ("OptionCare").

52. Trinity operates a home health care service in New York, New Jersey, and Florida. Trinity's services include nursing and clinical support, infusion therapy, and respiratory care. In addition to dispensing expensive home-delivered drugs, including Synagis, Trinity also provides medical equipment and supplies. The majority of Trinity's revenues during the relevant period came from New York's reimbursement of its Medicaid claims. Upon information and belief, Trinity also generated significant revenues from New Jersey and Florida for Synagis Medicaid claims.

53. Former Defendant OptionCare is a Delaware corporation with its principal place of business at 485 Half Day Road, Suite 300, Buffalo Grove, Illinois 60089. OptionCare is a wholly owned subsidiary of Walgreen Company, Inc. ("Walgreens"), which operates from its

headquarters in Deerfield, Illinois. Walgreens is a wholly owned subsidiary of Walgreens Boots Alliance, Inc., a holding company formed in 2014 when Walgreens merged with Switzerland-based Alliance Boots.

54. OptionCare provides its services through a network of more than 100 home infusion locations, 120 alternative treatment sites and respiratory therapy locations in 40 states. It has more than 2,000 employees. OptionCare also accounted for 58 acquired stores that were a major component of Walgreens' expansion program during its fiscal year ended August 31, 2007.

55. Trinity, OptionCare and Walgreens are collectively referred to herein as the Trinity Defendants.

56. At least 90 Walgreens specialty pharmacies are identified by MedImmune as authorized to dispense Synagis, some of which continue to operate under the OptionCare name. OptionCare/Walgreens operates in each of the States on whose behalf a claim is asserted.

57. Trinity's Medicaid provider number is 01858951 and its National Provider Identifier number is 1518036458. Throughout the acquisitions, Option Care of New York Inc. and Walgreen Co. continued to present Medicaid claims under the name and provider number of Trinity.

58. OptionCare and Walgreens established the Walgreens Specialty Pharmacy and the "Walgreens-OptionCare Synagis Simple Program."

59. From 2006-2011, Trinity was the top Synagis Medicaid biller in New York State, receiving more than $108 million dollars in reimbursement for its Medicaid claims for Synagis as compared to a total of $112.9 million dollars Medicaid paid to 58 other Medicaid pharmacy providers in New York during the same time period. The closest competitor pharmacy

dispensing Synagis to the Medicaid population only billed $18.1 million during this same time period.

60. OptionCare's profitability depended upon its relationship with MedImmune and the availability of Synagis. Synagis represented 9.5%, 7.3%, and 6.8% of OptionCare's total revenue, respectively, for the fiscal years ended December 31, 2006, 2005 and 2004. OptionCare's annual report for 2006 only mentioned one company by name, stating, "[t]he loss of our relationship with MedImmune, Inc. or with one or more other biotech pharmaceutical manufacturer would reduce our revenue and profitability."

61. In July 2015, the Trinity Defendants agreed to: 1) pay the State $22.4 million dollars in settlement of the State's and Relator's claims and 2) cooperate with "any investigation". *See* Dkt. No. 34 (July 9, 2015 Order). The State's investigation determined, *inter alia*, that:

- Trinity engaged in improper conduct and presented false Medicaid billings for the period 2007 through September 2011.
- The "majority" of Synagis dispensed by Trinity between 2007 and 2011 was for Medicaid patients.
- Relator alleged that Trinity "obtained baby names and other patient information from hospital NICU logbooks" and after the babies were discharged from the NICU, contacted the parents of former NICU patients to try to obtain them as Synagis clients.
- Relator alleged that Trinity made false statements and misappropriated her name and license to obtain Synagis for a baby she had never cared for. Trinity referred the baby to a home care nursing agency and falsely represented to the agency that

Relator had prescribed Synagis for the baby, which caused a Synagis shot to be administered to the baby. Trinity presented Medicaid claims to the State under Relator's name for both the dose that was administered and, a few weeks later, for a second dose that was not administered.

- Trinity used the names of other New York prescribers on alleged Synagis prescriptions and on Medicaid claims without authorization, and thereby dispensed Synagis for babies even when no prescriber had determined that the baby qualified to receive Synagis.
- Trinity staff called or sent letters to a baby's family, sometimes falsely representing that Trinity had been contacted by the baby's doctor to begin providing Synagis, which Trinity then represented to be extremely important to the baby's health. At times, Trinity then asked the family to verify information before sending the vial(s) for the first dose, even when Trinity had not received a Synagis prescription for such dose.
- At times, Trinity asked the family to provide the name of a baby's current medical provider or the outpatient clinic the baby was attending, and then tried to obtain a Synagis prescription order, regardless of whether the medical professional contacted was actually caring for the baby.
- The Trinity Defendants failed to ensure that Trinity complied with all applicable Medicaid rules and regulations, federal and state laws, regulations and policies in connection with Trinity's presentment of Synagis claims to the State, and that Trinity made accurate certifications to the State.
- The Trinity Defendants obtained rebates from MedImmune for their purchases of

Synagis related to their improper access to hospital NICUs.

D. Additional Relevant Non-Parties

62. BSS-CA1 is a former Biotech sales specialist who covered the Los Angeles County territory from 2004 through 2007.

63. BSS-CA1 and other MedImmune sales representatives provided doctors' offices' with binders to identify and track information about newborn babies. BSS-CA1 obtained PHI gained by accessing hospital NICU logbooks and/or patient logs at pediatricians' offices, and shared confidential information with Caremark for purpose of tracking babies and promoting Synagis.

64. BSS-CA2 is a former MedImmune sales representative who covered the southern California territory during 2011 and 2012.

65. BSS-CA2 and other MedImmune sales representatives accessed NICU logbooks at hospitals such as Long Beach Memorial and Fountain Valley Regional in California and used this PHI (a) to complete referral forms at hospitals and (b) track discharged babies through pediatricians in his territory.

66. BSS-CA3 is a former Biotech sales specialist who covered the Los Angeles County territory from 2006 through 2011.

67. BSS-CA3 and other MedImmune sales representatives were provided lists of babies being discharged from hospital NICUs, and maintained at pediatricians' offices binders to identify and baby track information and assist in completing referral forms.

68. MM-PA/NJ was an area Business Manager from 2007 to 2012 for Pennsylvania, and for a short period of time, part of New Jersey, who had two CMMs and 10 BSSs on his sales force.

69. MM-PA/NJ's salespeople accessed PHI at teaching hospitals in the Philadelphia area, and more specifically, Children's Hospital Philadelphia, UPMC Pittsburg, Pinnacle Hospital, Lancaster General, and St. Joseph Hospital. MM-PA/NJ's sales representatives used this protected information (a) to track discharged babies through pediatricians in his territory and (b) to complete referral forms at the doctors' offices. MM-PA/NJ met monthly with representatives from ARCO Pharmacy; a specialty pharmacy in Sharon Hill, PA to review how many doses were being sent to particular doctors, and in the process, he shared PHI with the pharmacy representatives.

70. BSS-OR is a former MedImmune sales representative who promoted Synagis sales from 2001 to 2009.

71. BSS-OR regularly received baby patient information from the Synagis coordinator at Legacy Emanuel Hospital in Portland, OR.

72. BSS-FL was a MedImmune sales representative from 2005 to 2009.

73. BSS-FL accessed confidential baby patient information at physicians' offices, which were maintained in Synagis binders at pediatrician's offices.

74. BSS-FL discussed babies' names and dates of birth with Caremark representatives, in connection with the preparation and approval of referral forms.

75. CVS Health, formerly known as the CVS Caremark Corporation, is a Fortune 500 American retail/specialty pharmacy and healthcare company headquartered in Woonsocket, Rhode Island. CVS' specialty pharmacy segment does business under the "Caremark" name throughout the United States, including the States that are the subject of Relator's claims.

76. Acro is a national specialty pharmacy that delivers customized healthcare management solutions. It was founded in 2006 and is based in Philadelphia at 313 Henderson

Drive, Sharon Hill, PA 19079, with a fulfillment center in Memphis, Tennessee. As of February 2011, Acro was a subsidiary of Lincare Holdings Inc. In 2016, Acro was acquired by NS3 Health, LLC, which is a subsidiary of Premier, Inc.

77. APS is a privately-held specialty pharmacy headquartered at 26611 Cabot Road, Suite B, Laguna Hills, CA 92653. APS reports to that it is one of the top Synagis providers in the United States, and the largest, single provider of Synagis to California-based Medi-Cal programs. APS' Synagis program has been expanded to Idaho, Washington, Wyoming, Montana and Alaska.

78. Between 2006 and 2011, APS representatives regularly met with MedImmune's District Sales Manager Craig Acerboni (Los Angeles territory) and/or MedImmune's Regional Business Director (West Region) David Boyd to exchange PHI. Describing its Synagis Management System, APS says: "Our diligent tracking and monitoring of patients receiving Synagis® is unsurpassed. **This includes looking closely at patients who marginally did not qualify to receive the mono-clonal antibody and looking for additional documentation and opinion that may otherwise qualify the patient."** This meant that APS was given PHI and was using it so that babies who had not been prescribed Synagis injections, and were given a Synagis prescription.

IV. GOVERNING LAWS AND REGULATIONS

A. The Federal False Claims Act

79. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

80. The FCA imposes liability upon any person who "knowingly presents, or causes

to be presented [to the Government] a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved." 31 U.S.C. § 3729(a)(1) and (2). Any person found to have violated these provisions is liable for a civil penalty of up to $11,000 for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government.

81. In general, the FCA imposes liability where the conduct is "in reckless disregard of the truth or falsity of the information" and further clarifies that "no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b).

82. The FCA also broadly defines a "claim" as one that "includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(c).

83. The FCA empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to intervene in the action. 31 U.S.C. § 3730(b).

84. A majority of states have enacted false claims acts or provisions that apply to Medicaid fraud and/or fraudulent health care claims submitted for payment by municipal funds (the "State False Claims Acts"). These include:

- California False Claims Act, Cal. Gov't Code § 12651 *et seq.*,
- Delaware False Claims and Reporting Act, 6 Del. C. § 1201 *et seq.*
- Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*
- Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*
- Illinois False Claims Act, 740 ILCS 175/1 *et seq.*
- Indiana False Claims and Whistleblower Protection Act, Burns Ind. Code Ann. § 5-11-5.5-1 *et seq.*
- Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5B *et seq.*
- Michigan Medicaid False Claims Act, Mich. Comp. Laws Serv. § 400.601 *et seq.*
- Montana False Claims Act; Mont. Code Anno. § 17-8-401 *et seq.*
- Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*
- New Jersey False Claims Act; N.J. Stat. § 2A:32C-1 *et seq.*
- New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*
- New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*
- Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.*
- Rhode Island False Claims Act; R.I. Gen. Laws § 9-1.1-1 *et seq.*
- Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.
- Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*
- Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*
- Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.*

85. The State False Claims Acts generally follow the federal FCA with respect to

liability and penalties.

B. The FDA Regulatory Scheme

86. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) & (d). Approval of the drug by FDA is the final stage of what is ordinarily a multi-year process of study and testing.

87. FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use for which the drug may be prescribed is called the "indication." FDA will specify particular dosages determined to be safe and effective for each indication.

88. The indication and dosages approved by FDA are set forth in the drug's labeling, the content of which is also reviewed by FDA. 21 U.S.C. §§ 352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. FDA will only approve the new drug application if the labeling conforms to the uses and dosages that FDA has approved. 21 U.S.C. § 355(d).

89. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses – *i.e.*, uses not listed on the approved label – the manufacturer must resubmit the drug for another series of clinical trials similar to those required for the initial approval. 21 U.S.C. § 360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is approved by FDA as described in the drug's

labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (*e.g.*, treating a child when the drug is approved to treat adults).

90. Although FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, FDA does not regulate the practice of medicine. Once a drug is approved, FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by FDA.

91. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by FDA. 21 U.S.C. §§ 331, 352.

92. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses.

C. Government-Funded Health Assistance Programs

1. Medicaid

93. The federal government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. *See* 42 U.S.C. § 1396a(a)-(b). Medicaid is implemented in 49 states, each of which has a state Medicaid agency to administer the program. The federal involvement in Medicaid includes providing matching federal funds and ensuring that states comply with minimum standards in the administration of the program.

94. Each state is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the HHS. Among other forms of medical assistance, the states are permitted to provide medical assistance from the Medicaid funds to eligible persons for inpatient and outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A), 1396d(a)(12). For example, New York enacted the Child Health Plus program ("Child Health Plus"), which is a state-funded public health insurance program for children operated by the New York State Department of Health and partially funded by federal law under the State Children's Health Insurance Program ("SCHIP"), codified in Title XIX of the Social Security Act (42 U.S.C. § 1396 *et seq.*). Depending on income, a family may be covered under Medicaid or Child Health Plus.

95. Medicaid providers pay pharmacies for prescription drugs. 42 U.S.C. § 1396a(a)(23) & (a)(32). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. *See* 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended. . . as medical assistance under the State plan." *See* 42

U.S.C. § 1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP"). Claims submitted to state Medicaid agencies are considered claims presented to the federal government and may give rise to liability under the FCA.

96. Moreover, Medicaid pays providers only for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3). "Covered drugs" do not include drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). A medically accepted indication is one "approved under the Federal Food, Drug, and Cosmetic Act" or included in certain, specified drug compendia. 42 U.S.C. § 1396r-8(k)(6). *See also* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for payment under the Medicaid program.

97. The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64) is the accounting statement which states, in accordance with 42 C.F.R. § 430.30(c), must submit each quarter under Title XIX of the Social Security Act. It shows the States' actual expenditures for the quarter being reported and previous fiscal years, the recoupment made or refunds received, and income earned on grant funds. These amounts, including the amounts paid for prescription drugs such as Synagis, have a direct effect on the amount of FFP that is paid by the federal government.

98. Each state Medicaid program has the power to exclude any drug from coverage if the prescription is not for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B).

D. HIPAA

99. HIPAA and the standards promulgated by the Secretary of Health and Human

Services ("Secretary") in the Code of Federal Regulations set forth the baseline for the release of PHI.

100. HIPAA's stated purpose of protecting a patient's right to the confidentiality of his or her individual medical information is a compelling federal interest designed to address the fear that electronically maintained medical records could be accessed and disseminated without the consent of patients.

101. In order to accomplish its stated goal, Congress delegated to the Secretary of HHS broad authority to promulgate rules and regulations protecting the privacy of PHI. The regulations place strict limitations on the ability of certain health care providers to release a patient's medical records or discuss the patient's medical history without the express consent of the patient. HIPAA-protected information may not be disclosed even where relevant to judicial and administrative proceedings, absent compliance with stringent requirements to protect the privacy of patient information. 45 C.F.R. § 164.512(e)(1).

102. Each violation of HIPAA is subject to a fine not to exceed $100. 42 U.S.C. § 1320d-5. Claims for payment for medical services provided to patients secured through HIPAA violations are improper under Medicaid and State and Federal FCA laws.

E. The Federal Anti-Kickback Statute

103. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration given to those who can influence health care decisions would result in the provision of goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect patients and federal healthcare programs, including Medicare and Medicaid, from these harms, Congress enacted a

prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Publ. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Publ. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93. 54.

104. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the Federal False Claims Act]."

105. According to the legislative history of the PPACA (and as interpreted by current jurisprudence), this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

106. Compliance with the AKS, 42 U.S.C. § 1320a-7b (b), is a condition of payment under federally funded health care programs, including State Medicaid program. Thus, Medicaid claims tainted by kickbacks are ineligible for payment under State and Federal FCA laws.

107. Violation of the AKS is also a felony punishable by fines and imprisonment, and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a- 7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7).

F. State Anti-Kickback Statutes

1. New York

108. Most States have an anti-kickback statute, regulations, and requirements that apply to its Medicaid program. Compliance with these statutes, regulations, and requirements are conditions of payment under that State's Medicaid program, and, like HIPAA violations, each State will not knowingly pay for Medicaid claims tainted by kickbacks. For example, New York's statutes, regulations, and requirements include: New York, 18 N.Y.C.R.R. § 515.2(b), § 518.1(c), Soc. Serv. Law § 366-f, and the N.Y.S. Medicaid Provider Manual, Information for All Providers – General Policy. Further, reimbursement by the government is only made when providers execute a Medicaid claim Certification Statement as to the propriety of their claims and compliance with law.

109. Trinity was an enrolled Medicaid provider. Medicaid regulations require that "[a]ny person who furnishes medical care, services or supplies for which payments under the [Medicaid] program are to be claimed; or who arranges the furnishing of such care, services or supplies; or who submits claims for or on behalf of any person furnishing or arranging for the furnishing of such care, services or supplies must enroll as a provider of services prior to being eligible to receive such payments, to arrange for such care, services or supplies or to submit claims for such care or supplies." 18 NYCRR § 504.1(b)(1).

110. Trinity executed such Certification Statements during the relevant period and provided these documents to New York, and executed and provided similar certifications to New Jersey and Florida. As a condition of enrollment and as a condition of payment of claims presented to Medicaid, providers must affirmatively certify compliance with applicable federal and state laws and regulations and that the services provided were "medically necessary."

111. A provider must renew the Certification Statement periodically by signing a new Certification Statement. The Certification Statement last signed by the provider remains in effect for all claims until a new Certification Statement is signed by the provider.

112. 18 N.Y.C.R.R. § 515.2(b) specifically prohibits as an "unacceptable practice": (5) Bribes and Kickbacks . . .

> (ii) soliciting or receiving either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program;
>
> * * *
>
> (iv) offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program.

* * *

113. 18 N.Y.C.R.R. § 515.2(a) also specifically prohibits as an "unacceptable practice" conduct that is contrary to:

> (3) the official rules and regulations of the Departments of Health, Education and Mental Hygiene, including the latter department's offices and division, relating to standards for medical care and services under the [Medicaid] program; or
>
> (4) the regulations of the Federal Department of Health and Human Services promulgated under title XIX of the Federal Social Security Act.

114. Pursuant to 18 N.Y.C.R.R. § 518.1(c) "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake."

115. Title 18 provides further that "[n]o payments will be made to or on behalf of any

person for the medical care, services or supplies furnished . . . in violation of any condition of participation in the program," nor will payments be made for "for any medical care, services or supplies ordered or prescribed in violation of any condition of participation in the program." 18 N.Y.C.R.R. § 515.5(a), (b). Accordingly, all claims for payment to Medicaid resulting from kickbacks are in violation of a material condition of payment of the New York State Medicaid Program.

116. MedImmune violated the law by, *inter alia,* engaging in the kickback scheme with Trinity and by knowingly causing Trinity to present false claims for reimbursement to Medicaid, which rendered Trinity's Certification Statements false.

2. California

117. California's anti-kickback law makes it illegal for one licensed in the healing arts[3] to receive or provide kickbacks, stating:

> [T]he offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest, or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

Cal. Bus. & Prof. Code § 650(a).

118. Moreover, California's Aid and Medical Assistance Statute—which governs programs such as Medi-Cal, California's Medicaid program—makes it illegal for a provider to receive or provide kickbacks, stating:

[2] The "healing arts" includes "pharmacy." *See* Cal. Bus. & Prof. Code Div. 2, Ch. 9.

a) Any person who solicits or receives any remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind, either:

1) In return for the referral, or promised referral, of any individual to a person for the furnishing or arranging for the furnishing of any service or merchandise for which payment may be made, in whole or in part, under this chapter or Chapter 8 (commencing with Section 14200); or

2) In return for the purchasing, leasing, ordering, or arranging for or recommending the purchasing, leasing, or ordering of any goods, facility, service or merchandise for which payment may be made, in whole or in part, under this chapter or Chapter 8 (commencing with Section 14200), is punishable upon a first conviction by imprisonment in a county jail for not longer than one year or imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by a fine not exceeding ten thousand dollars ($10,000), or by both that imprisonment and fine. A second or subsequent conviction shall be punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code.

b) Any person who offers or pays any remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind, either:

1) To refer any individual to a person for the furnishing or arranging for furnishing of any service or merchandise for which payment may be made, in whole or in part, under this chapter or Chapter 8 (commencing with Section 14200); or

2) To purchase, lease, order, or arrange for or recommend the purchasing, leasing, or ordering of any goods, facility, service, or merchandise for which payment may be made, in whole or in part, under this chapter or Chapter 8 (commencing with Section 14200) is punishable upon a first conviction by imprisonment in a county jail for not longer than one year or pursuant to subdivision (h) of Section 1170 of the Penal Code, or by a fine not exceeding ten thousand dollars ($10,000), or by both that imprisonment and fine. A second or subsequent conviction shall be punishable by imprisonment

> pursuant to subdivision (h) of Section 1170 of the Penal Code.
>
> * * *
>
> d) For purposes of this section, "kickback" means a rebate or anything of value or advantage, present or prospective, or any promise or undertaking to give any rebate or thing of value or advantage, with a corrupt intent to unlawfully influence the person to whom it is given in actions undertaken by that person in his or her public, professional, or official capacity.
>
> e) The enforcement remedies provided under this section are not exclusive and shall not preclude the use of any other criminal or civil remedy.

Cal. Wel. & Inst. Code § 14107.2.

2. California's Health and Safety Code states:

> No person, firm, partnership, association or corporation, or agent or employee thereof, shall for profit refer or recommend a person to a physician, hospital, health-related facility, or dispensary for any form of medical care or treatment of any ailment or physical condition. The imposition of a fee or charge for any such referral or recommendation creates a presumption that the referral or recommendation is for profit.

Cal. Health & Safety Code § 445.

119. Other relevant state anti-kickback statutes, [which are substantially equivalent to New York and California] include:

- 31 Del. Code Ann. § 1005
- Fla. Stat. § 456.054
- Fla. Stat. § 409.920
- 720 ILCS 5/33E-7
- Ind. Code § 12-15-24-2

- Mass. Gen. Laws ch. 118E § 41
- Mass. Gen. Laws ch. 175H § 3
- Mich. Comp. Laws § 400.604
- Mont. Code Ann. § 45-6-313
- Nev. Rev. Stat. § 422.560
- N.J. Stat. Ann. § 30-4D-17
- N.M. Stat. Ann. § 30-41-1
- N.M. Stat. Ann. § 30-44-7
- 56 Okla. Stat. Ann. § 1005
- 63 Okla. Stat. Ann. § 1-742
- R.I. Gen. Laws § 40-8.2-3
- Tex. Hum. Res. Code § 32.039
- 1 TAC § 371.1669
- Va. Code Ann. § 32.1-315
- Wis. Stat. § 946.91

V. FACTUAL ALLEGATIONS

A. MedImmune Grows Rapidly Due to Synagis

120. Defendant MedImmune manufactures and markets Synagis (palivizumab), a brand-name prescription drug approved to reduce the severity of lung infections caused by RSV in at-risk children. Synagis is injected into infants intramuscularly once per month during the RSV season.

121. Synagis received FDA approval in 1998 and quickly became MedImmune's

largest-selling drug. The Company's sales staff marketed the drug to pediatricians, hospitals, and parents as a treatment to reduce the symptoms of RSV, which can lead to hospitalization for bronchiolitis or pneumonia. For 2000, sales totaled $427 million, accounting for 79% of the Company's revenues. By 2004, U.S. sales of Synagis had more than doubled to $834 million, and continued to climb in 2005 and 2006. Synagis represented over 87% of MedImmune's overall product sales in 2006.

122. MedImmune's national sales force then included 270 sales representatives who focused on pediatricians plus 92 salespeople who visited hospitals. This included 125 new sales professionals hired in advance of the 2006/2007 RSV season, as MedImmune's co-promotion agreement with Abbott Laboratories expired and MedImmune assumed full responsibility for promoting Synagis in the U.S.

123. In June 2007, British drug-maker AstraZeneca acquired MedImmune for $15.6 billion. MedImmune became the hub of its biologics division. AstraZeneca immediately invested substantial capital and scientific resources in Synagis. The number of MedImmune employees soared from 1,700 to over 4,000, with the vast bulk of the Company's revenues still generated by Synagis.

B. MedImmune's Sales Force Focused On Identifying and Tracking Infants By Providing Valuable Services and Leads

124. MedImmune provided valuable services, information and renumeration to hospitals, pediatricians, and specialty pharmacies such as Trinity, APS, Acro, and Caremark in order to increase sales of Synagis and cause the submission of false claims to Medicaid. These services included (i) "helping the staff" track discharged babies that were likely candidates for Synagis; (ii) completing required paper work such as referral forms and other documentation

needed to prescribe Synagis; (iii) providing lunches to physicians and their staff that prescribed Synagis; (iv) providing binders and forms to physician offices; (v) compensating neonatologists for speaking about RSV and Synagis; and (vi) using PHI as valuable leads or referrals to the specialty pharmacies, as well as valuable administrative services and sales rebates.

125. MedImmune operated a national sales force. The Company sales representatives called Clinical Marketing Managers ("CMM") focused on hospitals, while those called Biotech Sales Specialists ("BSS") generally concentrated on pediatrician offices. However, both CMMs and BSSs coordinated, often working in tandem at the hospitals to obtain baby PHI from the NICU logs. The sales forces' efforts were enhanced by the doctors who were paid to be speakers at functions or were sponsored to do videos promoting Synagis use. These doctors were generally recruited as paid promotors if they were liberal prescribers of Synagis (*i.e.*, "extra doses") or high volume prescribers of Synagis.

California

126. BSS-CA1 explained that during her tenure (2004-2007) she spent time in the hospitals during what she termed "ground rounds." The "ground rounds" were a process that occurred approximately once or twice per quarter. This process involved the MedImmune sales representative, such as BSS-CA1, working with their local CMM or going on their own to meet and greet key staff at the hospitals in their respective territories. The key hospital staff included NICU nurses, discharge nurses, neonatologists or other hospital staff with whom a relationship could lead to access to NICU logbooks. BSS-CA1 worked hospitals closely with CMM Cynthia Scott in Los Angeles.

127. According to BSS-CA 1, neonatologists from the NICUs were paid speakers for

MedImmune. Other MedImmune-sponsored doctors provided videos promoting Synagis, including "extra doses."

128. BSS-CA1 stated that identifying babies as candidates for Synagis doses was the way that the sales staff at MedImmune set themselves up to attain assigned sales goals. Numerous babies born prematurely in the summer months before the RSV season started – in or around October -- did not receive their first Synagis doses in the NICU. According to BSS-CA1, their PHI would be used as leads to track them or give referrals to pharmacies. There were also some babies who were born very prematurely, whose PHI was used to promote a second round of Synagis dosing to the physicians and/or parents the following year.

129. BSS-CA1 reported that accessing patient data was critical to track these babies. The most common ways that these babies were identified and tracked was through reviewing the NICU logbooks and reviewing the patient logs at doctors' offices. Both of these sources of patient data – were of equal importance to the sales staff at MedImmune.

130. In addition, when the MedImmune representatives forged relationships with NICU staff, they were more likely to generally be able to get in to the NICUs and "see the babies and the pediatricians who were treating them," so that they had a secondary source for identifying babies as potential patients for Synagis.

131. BSS-CA3 confirmed that identifying all of the premature babies who were discharged from the NICU at each hospital, tracking babies and assisting with the completion of referral forms to pharmacies to dose Synagis was the main job of the BSSs. This later task was accomplished by working with the staff at the pediatricians' offices. This was an important means for BSS-CA3 and the other BSSs to attain their sales goals. The sales goals set by

management were "aggressive," and not attainable unless the sales force followed through on the tactics for accessing baby patient information.

132. BSS-CA1 emphasized that the whole sales projection process at MedImmune was based on obtaining this information. Area Business Manager Bill Churchill asked for specific details in sales meetings about how many babies there were in each NICU at each hospital for the purpose of sales projections. If the CMMs did not have this information Churchill and other managers would have thought the CMMs were not doing their jobs.

133. For example, BSS-CA1 stated that the hospital staff at St. Francis Medical Center in Lynwood, California allowed MedImmune's CMM representative, Cynthia Scott, access to the NICU logbooks. In addition, two doctors with offices near St. Francis Medical Center allowed BSS-CA1 to access their patient logs.

134. BSS-CA1 stated it was "huge" to have the necessary relationships with hospital staff at St. Francis and another Los Angeles County hospital, Cedars-Sinai Medical Center. According to the witness, these hospitals had a high number of low-income patients, including Hispanic mothers covered by MediCal. Many of the low-income mothers gave birth prematurely. St. Francis, in particular, was a Catholic hospital where low-income women, some traveling there from out of the area, sought to give birth to their babies. Those babies were discharged to various doctors, some nearby St. Francis, and some out of the area, depending on where the mothers resided.

135. BSS-CA3 reported that a member of the NICU staff at St. Francis would provide BSS-CA3 with lists of babies who were discharged about every six weeks so BSS-CA3 could track them.

136. After the CMM position was created, the CMM typically supplied the biotech sales specialists with the NICU baby data, and then the BSS used the data to follow-up with pediatricians to ensure that each baby had been accounted for and was being dosed with Synagis. MedImmune sales people continued to assist with the completion of referral forms. Area manager Acerboni was aware of and authorized this practice.

137. BSS-CA3 stated she learned after her employment ended that these practices at MedImmune were not common or customary in the industry. BSS-CA3 explained that instead of calling on doctors to talk about the virtues of the product being promoted (in this case, Synagis), the biotech sales specialists at MedImmune were tasked with "finding patients and getting on the therapy [Synagis]."

138. BSS-CA1 observed that PHI information was deliberately not conveyed via email because the MedImmune sales staff should not have had the data in the first place. Instead, the CMM who covered BSS-CA1's territory, Cynthia Scott, held regular meetings at her house. During these meetings, Scott informed at least one other biotech sales specialist, Chad Mierau of the names of babies who had been discharged from St. Francis Hospital, for instance.

139. BSS-CA3 also concluded that the sales staff met at Scott's house and avoided emails because of the improper nature of the activity in which they were engaged. BSS-CA3 confirmed receiving patient data covering babies that were discharged from the NICUs in paper copy, in the form of a list, when she met with the CMM in the field.

140. BSS-CA1 confirmed that the biotech sales specialists were charged with going around to the doctors on which they called to ensure that those babies the CMM (here Scott) identified as discharged were being seen by one of the pediatricians on whom they called, and

that those babies were dosed with Synagis.

141. BSS-CA1 also reported that CMM Debbie Foley, who covered the Beverly Hills territory, was particularly successful at identifying babies who were candidates for Synagis because of her relationships at Cedars-Sinai. Foley, a nurse, knew how to read patient charts, which added to her success in using patient data to identify potential Synagis patients.

142. BSS-CA2 confirmed that while he was responsible for calling on doctors in the Los Angeles area, he also spent time in some of the local hospitals during his tenure (2011-2012), including Long Beach Memorial and Fountain Valley Regional. BSS-CA2 said that there was a mix of patients at these hospitals including beneficiaries of California's Medicaid program.

143. BSS-CA2 went to the hospitals at least a few times per week and accessed the logbooks during the normal course of these visits. As part of his relationship, he provided assistance to the hospitals by completing referral forms. Prescriptions for Synagis could not be filled until the forms were accurately completed.

144. BSS-CA2 not only accessed the logbooks to get the necessary information to complete the referral forms, but also looked at the logbooks and recorded babies' information for his own use to track patients for future shots of Synagis. He transcribed the babies' names and dates of birth onto a "piece of paper" that he kept handy. BSS-CA2 then used the babies' identifying information to call on doctors in his territory about those babies and Synagis doses.

145. BSS-CA1 explained that some doctors viewed MedImmune representatives as providing a "service" that was beneficial to the doctors. The staff of those doctors treated BSS-CA1 and other MedImmune sales representatives as if they were helping in the process of

identifying and tracking the patient population who were candidates for Synagis doses.

146. Long-time members of MedImmune's sales force established standard techniques for obtaining PHI and tracking babies post-discharge. BSS-CA2 said he essentially imitated the practices of sales representative Monica Goodale and another representative in terms of accessing the logbooks and writing down the babies' information for the purposes of tracking those patients.

147. BSS-CA3 reported that Area Business Manager Acerboni was aware of these practices and often encouraged them. BSS-CA3 went on many "ride alongs" with Acerboni during BSS-CA3's employment. On several occasions, BSS-CA3 informed Acerboni that BSS-CA3 was going into a particular doctor's office because the staff there "needed help completing the referral form." Acerboni did not object to BSS-CA3's actions during these ride alongs. Instead, he informed BSS-CA3's that he would wait in the car and that she should "do whatever she needed to".

148. BSS-CA3's also reported that Acerboni also made references to his sales staff during regular sales meetings that the team members should "do whatever they needed to do" in order to attain their sales goals.

149. It was the practice of most experienced MedImmune sales representatives to maintain a "Synagis binder," which compiled PHI from, NICU logbooks and from hospital and pediatric staff. BSS-CA1 also first learned about the binders during interactions with more veteran representatives, including during ride along with the veterans. These veteran representatives included Debbie Foley, the representative who covered Cedars-Sinai hospital.

150. BSS-CA1 explained that the binders contained PHI details for each patient.

Similar to the practice of sales managers in New York as described herein, BSS-CA1's area business manager Bill Churchill, and later his replacement, made reference to the binders during sales meetings. These managers encouraged the sales representatives to make sure they were using their binders. "Everyone was very open" at MedImmune about the fact that they maintained these binders and used them to "track patients."

151. BSS-CA1 knew it was common practice for biotech sales specialists to assist physicians and their staff with the completion of referral forms based on discussions she had with colleagues and from various discussions that came up about the process during sales meetings.

152. BSS-CA3 stated that, based on discussions with other MedImmune sales representatives, the APS specialty pharmacy representative "met a lot" with Acerboni and/or Regional Director David Boyd. BSS-CA3 explained that APS "carried so much of the business in Los Angeles" that it was critical that MedImmune senior sales manager meet with the APS representatives to discuss patient data and ensure that all of the pieces were in place for vials to be delivered on schedule. If the process was "managed efficiently," it took "two weeks" for the vials to be supplied to the doctors. Any hiccups in the process meant that the vials might not be delivered for "eight weeks," which could cause babies to miss their scheduled doses of Synagis. This meant lost sales for MedImmune and APS.

153. BSS-CA3 reiterated biotech sales specialists regularly helped the staff at pediatricians' offices to complete referral forms. BSS-CA3 explained that this assistance included reviewing the referral forms, giving the staff advice on how to complete them, and even "writing" the referrals at times. The biotech sales specialists only stopped short of "signing them [the referral forms]." It was important that the referral forms were accurately completed because

any issues with these forms delayed dosing of Synagis.

154. The lists of baby names and their demographic information were things of value that MedImmune shared with pharmacies such as Trinity, APS, and Caremark. Leads initially required follow-up on missing personal and demographic information which required contact with the baby's future pediatrician upon discharge from the NICU, prior to the next RSV season. This valuable information constituted a kickback, used for the mutual benefit of MedImmune and the specialty pharmacies by increasing Synagis sales. *See* State Cmpt. ¶92.

155. BSS-CA1 stated that BSS-CA1 and the other MedImmune representatives were the "work horses" for Caremark. BSS-CA1 and other MedImmune representatives viewed Caremark as a "colleague." They shared PHI with the Caremark representatives, but often not in writing. BSS-CA1 and other MedImmune representatives called the Caremark representative and/or talked when their paths crossed in the field. The MedImmune personnel advised the Caremark representative of the number of babies who were Synagis candidates and identified the pediatricians who would be treating them. In some instances, however, BSS-CA1 and the other MedImmune representatives also shared the names of babies with the Caremark representative.

Pennsylvania / New Jersey

156. Medimmune's improper and illegal sales practices were Companywide. MM-PA/NJ, the Area Business Manager from 2007 to 2012, for Pennsylvania, and for a short period of time, a part of New Jersey, reported that during his tenure, there was a strategic effort led by Scott Cramer, then MedImmune's Vice President of sales, and others to ensure that MedImmune "tracked" babies from the point of discharge from the NICUs and pediatric intensive care units ("PICUs"), all the way through to dosing at the pediatricians' offices. MM-PA/NJ understood

that the tracking process had been in place "since inception," meaning that it was used by MedImmune sales staff from the time the company began selling Synagis in approximately the late 1990s.

157. MM-PA/NJ reported to Jerry O'Malley, who was one of three or four Regional Directors at MedImmune, who formerly served as the Area Business Manager in Pennsylvania. O'Malley reported to National Sales Manager Mark Hitz, who reported to Scott Carmer. MM-PA/NJ led a sales force that included 2 CMMs: specifically, Rich Bodinizzo and Paul Portugalo, and 10 BSSs.

158. The entire tracking process was planned and managed via business plans – both annual business plans for the territory MM-PA/NJ managed and more frequently reviewed business plans that were regularly updated with the results of sales efforts from the field.

159. The regional directors and area business managers completed an annual business plan as a means of projecting sales. The field based staff also used a variation of the business plan to track their progress to goal. MM-PA/NJ met with members of his field staff throughout the week, usually at a Panera Bread or Starbucks location early in the morning, at around 7:30 or 8:00 a.m. These were typically one on one meetings with MM-PA/NJ and a clinical marketing manager or biotech sales specialist he supervised. MM-PA/NJ's staff members brought their documentation with them to show how many babies they were tracking and how or whether they expected to attain their assigned sales goals based on the number of babies they had "in the funnel."

160. MM-PA/NJ stated Medicaid babies were an important source of potential babies in the "funnel." He emphasized, "We wanted Medicaid babies" because the mothers of these

babies were often uneducated and easy to coach in what information, symptoms or environmental factors to specify in order to improve chances of approval.

161. MM-PA/NJ was invited to executive level meetings after he was tasked with working on the new business plan template for MedImmune. as part of a Sales Professional Development Program that was implemented by Carmer in approximately 2010 or 2011. The business plan, ultimately rolled out at the national sales meeting in Las Vegas in 2011, was an Excel-based form. The Excel template had 13 pages that covered various aspects of sales planning, patient identification and tracking, and a means for recording actual results and explaining the variances between projections and results

162. These meetings were regularly attended by Carmer, Topher Brooke, and the Chief Financial Officer (Tim Gray). The meetings were held at the Bonefish Grill in a strip mall across from the Gaithersburg, Maryland MedImmune headquarters. MM-PA/NJ attended at least 6 of these meetings beginning in 2011.

163. During the meetings, the executives spoke very openly and candidly about MedImmune's tracking practices. There was often a fair amount of alcohol consumed by the meeting attendees. And, during the meetings, Vice President of Sales Carmer regularly asked for "honest" feedback about the obstacles in the field that prevented MedImmune from achieving higher sales of Synagis. At times during these meetings, MM-PA/NJ and/or other attendees told Carmer that there were problems with representatives not identifying or tracking enough babies, or not reviewing enough charts. Carmer's typical advice in response was to instruct that the sales team find a way for the sales staff to identify and track more babies and review enough charts to improve sales.

MedImmune's Tracking Process

164. MM-PA/NJ explained that MedImmune employed a strategic "tracking" practice to follow all babies discharged from NICUs. When MM-PA/NJ joined MedImmune in 2007, he took over a team that had been well-oiled by O'Malley. That is, the two clinical marketing managers and 10 biotech sales representatives MM-PA/NJ oversaw in Pennsylvania were already well accustomed and had standard practices for accessing patient data at the NICU or PICU level, and sharing that data among the team for the purposes of tracking the babies.

165. MM-PA/NJ explained that the term "tracking" was used regularly among management at MedImmune to refer to the process through which babies were identified at the point of discharge by the hospitals and later closely followed by the biotech sales specialists in the field. The purpose of this "tracking" practice was to identify as many potential Synagis patients as possible. As MM-PA/NJ explained, MedImmune management knew and took the approach that the more babies who were possibly eligible for Synagis that were identified and tracked, the better the chances that more babies would ultimately be dosed. Or, as MM-PA/NJ put it, "the more babies in the funnel," the more patients were ultimately approved for Synagis.

166. The tracking process began as soon as the RSV season ended for the previous year. Immediately thereafter, the sales staff began identifying and tracking babies who would potentially be eligible for Synagis when the new RSV came about in or around October. Through the tracking process, the sales managers knew if they were going to "hit their numbers or not within the first two months of the [RSV] season."

167. Medicaid babies were an important source of potential babies in the "funnel," as MM-PA/NJ explained. MM-PA/NJ emphasized, "We wanted Medicaid babies" because the

mothers of these babies were often uneducated and easy to coach in what information, symptoms or environmental factors to specify in order to improve chances of approval. MM-PA/NJ recalled that the biotech sales specialists held "parent meetings" at the doctors' offices during the first two years of MM-PA/NJ's employment. During these meetings, the sales specialists spoke to the parents about "how to get approved." MedImmune disallowed these meetings in approximately 2009, but MM-PA/NJ did not know the circumstances that led to this change.

168. MM-PA/NJ emphasized that Bodinizzo and Portugalo were "at the top of their craft," and had the necessary relationships in place at the hospitals they covered to ensure access to patient data. Portugalo had worked in the territory for some time before MM-PA/NJ joined MedImmune, and Bodinizzo had worked for O'Malley for an extended period of time. Both of these clinical marketing managers understood their roles and responsibilities before MM-PA/NJ joined the team. The clinical marketing managers went to the hospitals they covered "every day." The clinical marketing managers were able to cover two or three hospitals in a day.

169. Once the biotech sales specialists received the discharge forms, they were tasked with ensuring that each baby identified in a discharge form was accounted for among the charts and binders maintained at the pediatrician offices on which they called. MM-PA/NJ explained that the average amount of time in the industry that a pharmaceutical sales representative spends at a doctor's office is very short. It is common practice in the industry for pharmaceutical sales representatives to wait in the lobby of the doctors' offices, until the doctors allow the representatives into the back area where patients are seen or where the doctors' have their private rooms. Even then, the sales representatives at most pharmaceutical companies are only with the doctors for maybe 30 seconds. By contrast, the MedImmune sales representatives spent an hour

or longer, on average, during each visit to the doctors on which they called. This time was spent reviewing charts, making recommendations for the doctors and their staff about babies who might be eligible for Synagis, completing referral forms, and coaching the staff about ways the charts should be documented in order to increase the likelihood of insurers approving Synagis for the babies. MM-PA/NJ emphasized that the sales staff knew all aspects of each insurers' approval criteria, including Medicaid, and reviewed files and coached doctors and their staff on the best methods to ensure dosing approval based on the type of insurance the patients carried.

170. One way that the MedImmune sales staff coached doctors and their staff was by asking the doctors if they recalled the babies having a "raspy" cough or if the babies had any "diaphragmatic issues." According to MM-PA/NJ, some of the doctors saw as many as 10 to15 patients per day, and there was no way they could recall if one particular baby had a "raspy" cough. However, when the MedImmune representatives asked the doctors these questions enough times, the doctors finally caught on to the fact that if they made notes in the patients' charts about such "raspy" coughs or "diaphragmatic issues," the patients were more likely to be approved for Synagis dosing.

171. MM-PA/NJ also said that physicians' receptionists were also invited to lunches paid for by MedImmune. One reason why the receptionists were included in the lunches was because doing so afforded the opportunity for the MedImmune biotech sales specialists to advise receptionists to be listening to conversations between mothers of possible Synagis patients to see if they mentioned, for instance, coal furnaces or wood burning stoves in their homes. The MedImmune representatives knew that the existence of these heating sources could be noted in patient charts as contributing factors to breathing problems for the babies, which then made the

babies more likely to receive approval from the insurance/payers for doses of Synagis, Medicaid included.

172. In addition to coaching the doctors and/or their staff members, the biotech sales specialists reviewed patient data both in patient charts and in Syangis binders maintained in the doctors' offices. MM-PA/NJ noted that one role of the biotech sales specialists was to review patient charts and signify to the doctors and their staff members which babies were likely eligible for Synagis. This signification was made by the biotech sales specialist placing "Synagis stickers" – or stickers that said Synagis on them – on charts of babies who the MedImmune representatives believed could be eligible for Synagis. These stickers were round in shape, with blue and some pink coloring on them, reflecting the MedImmune logo colors. The stickers were ordered in rolls by MedImmune and carried by the sales specialists in their bags or brief cases. Each sticker was approximately an inch or two in size. The design of the stickers was such that they "stood out like a sore thumb" and "could not be missed" by the doctors or their staff members because they were the only colorful item among a file of white paper in the patients' files.

173. There were Synagis binders maintained in the doctors' offices, which MM-PA/NJ said were regularly referred to as "tracking binders." These were binders that were purchased by the MedImmune biotech sales specialists, using MedImmune funds. The binders were maintained by a Synagis "coordinator or champion" in the doctors' offices, and contained various patient identifying data in the form of discharge forms. The binders also detailed the type of insurance each patient carried, the number of babies dosed with Synagis by the doctor's office year over year, and the current dosing schedule for the babies seen in the office where the binder

was maintained. The MedImmune sales representatives had access to these binders and regularly reviewed the data in them for various reasons.

174. In addition, the MedImmune biotech sales specialists also completed referral forms for patients, as a service to the doctors and their office staff. According to MM-PA/NJ, it was very common for the MedImmune biotech sales specialists to complete the referral forms, with the exception of signing them. He witnessed representatives in his territory completing the forms. The biotech sales specialists completed referral forms for the doctors' staff, most often because the MedImmune sales specialists knew the insurance guidelines very well, including Medicaid, and knew what information to include in the referral forms to ensure that they were approved.

175. This entire tracking process was planned and managed via business plans – both annual business plans for the territory MM-PA/NJ managed and more frequently reviewed business plans that were regularly updated with the results of sales efforts from the field. The field staff members were evaluated by the area business managers based on the number of calls they made to offices per day, the number of calls per week, and how many babies they "tracked and identified." And, even the criteria for the number of babies "tracked and identified" was broken down further to the level of the gestational age of the babies and whether there were any factors that were identified for each baby that made the baby more likely to be approved for Synagis.

176. MM-PA/NJ explained that babies with particular breathing issues received "Cafcit," or a particular drug given to babies in the NICU to treat lack of breathing. The clinical marketing managers sought for the NICU staff to note when Cafcit was given to babies on this

discharge forms because babies who were treated with Cafcit were more likely to be approved for Synagis. Among criteria used to evaluate the performance of the sales staff, it was most important that the representatives captured these little details, such as prior Cafcit dosing, and ensured that these details made it to the patient charts. This was important because this increased the chances that more babies "from the funnel" would ultimately be approved for Synagis dosing. As such, it was not just important for the sales staff to identify and track patients, but it was also part of the biotech sales specialists' responsibilities to know what made approval more likely and ensure that these factors that improved the chances of approval were documented in patient files.

177. MM-PA/NJ pointed out that Regional Director O'Malley had invented a term, "lateral leadership," to describe a process whereby the clinical marketing managers taught the biotech sales specialists how to capitalize on notes in the discharge paperwork. For instance, the clinical marketing managers used "lateral leadership" to instruct the biotech sales specialists to ensure that notes about Cafcit in the discharge paperwork were transferred to the patient's file maintained at the pediatrician's office.

178. As described further below, MM-PA/NJ was actually responsible for developing the templates for the business plan in the latter part of his employment. He noted that the language chosen for the fields of the business plans were strategically chosen in conjunction with an employee from compliance. The language was put into drop down menu options for populating the business plans, so that no sales representatives could populate the plans with details of their jobs that made it obvious they were engaged in non-compliant activity.

179. Over the course of MM-PA/NJ's employed with MedImmune, the company made various changes to the practices and language that comprised the "tracking process." As MM-

PA/NJ emphasized, these changes were all a farce to make it outwardly appear that MedImmune was compliant with HIPPA and other guidelines. However, the actual activity in the field was never really modified, and patient data was accessed and used to identify and track potential Synagis patients throughout the duration of MM-PA/NJ's employment. Most of the changes described in this section of the report were implemented in 2009. MM-PA/NJ recalled that they were implemented in 2009 because this was also the time that the American Academy of Pediatrics implemented new, more stringent guidelines for Synagis eligibility. The Academy of Pediatrics issued new guidelines every two years. And, in years prior, MM-PA/NJ said that MedImmune had tried to predict the changes and stay ahead of them by coaching the doctors and their staff on the best means for chart documentation in order to improve chances of approval. One example of the changes that were in this 2009 timeframe was a change in the "verbiage" that was used internally at MedImmune to describe the tracking process. When MM-PA/NJ first joined MedImmune in 2007, the process was commonly referred to as "patient tracking." This was language that was used, for example, in conference calls that took place between O'Malley and the area business managers who reported to him every Friday. This language was also used in discussions between the area business managers and their clinical marketing managers and biotech sales specialists.

180. MM-PA/NJ had a sales call with his sales staff every Monday. During these meetings, he regularly discussed any changes that were announced by O'Malley during the weekly conference calls that took place on Friday. On one of these Friday conference calls in or around 2009, O'Malley announced that the term "patient tracking" could no longer be used. Instead, O'Malley instructed that the practices in which the sales staff engaged to identify and

track patients could only be referenced as "patient identification." There was some loophole in the regulatory requirements that made patient identification legal in some aspects. Therefore, MedImmune management had determined that the company was best served and most protected from anyone discovering the non-compliant activity at the company if the term "patient identification" was used in lieu of "patient tracking." However, the actual processes of identifying babies being discharged by the hospitals and tracking these patients at the pedictricians' offices, as described above, did not change. As MM-PA/NJ further clarified, it was no different than the old "tomayto, tomahto" adage, whereby no matter what one called it, the words still described the same thing.

181. At one time in or around 2009, O'Malley also instructed his area business managers to refer to the discharge forms as "hand off forms." And, yet another change that occurred around or after the new American Academy of Pediatrics Synagis eligibility guidelines were implemented in 2009 related to how the biotech sales specialists accessed patient charts at the pediatricians' offices. MM-PA/NJ recalled that there was a directive from management in approximately 2009 that mandated the biotech sales specialists were no longer allowed to pull patients charts on their own for review. However, this did not stop the sales specialists from accessing charts. Rather than pulling the charts, the sales specialists just arranged for the doctors' staff to pull the files and leave them in folders on desks in the offices where the sales specialists could access and review them.

182. In this same timeframe, the biotech sales specialists were also no longer allowed to use the Synagis stickers. This did not stop the specialists from reviewing patient files and making recommendations about patient eligibility, though. Instead of using the stickers, the

representatives just began placing the Synagis package insert in the files of patients who they believed were likely eligible for dosing of the product. And, within a short period of time, the sales specialists were then no longer able to put the package inserts in the patient files, and began just paper-clipping the package inserts to the outside of the files to signify likely eligibility for Synagis to the doctors and/or their office staff members.

Accessing and Communicating PHI from Hospital NICUs

183. When MM-PA/NJ joined MedImmune in 2007, his sales staff routinely obtained PHI for tracking purposes from hospitals such Children's Hospital Philadelphia, UPMC Pittsburg, Pinnacle Hospital, Lancaster General, and St. Joseph Hospital.

184. The tracking process began with the clinical marketing managers accessing PHI of babies being discharged from the NICUs and PICUs. The practice of accessing patient data occurred at nearly every hospital across the country where MedImmune operated. This process included the clinical marketing managers accessing files at large "teaching hospitals" such as Children's Hospital, Lancaster General and Saint Christopher's. Patient files were left for the CMMs in the academic offices of doctors who treated premature babies at some of the large teaching hospitals in Pennsylvania. Some of the neonatologists and other staff at the large teaching hospitals maintained academic offices on the hospital campuses, and found it to be less risky to leave files for the clinical marketing managers in their academic offices (as opposed to letting the clinical marketing managers into the NICUs or PICUs) in order to access PHI. This was less risky because there was reduced risk of the clinical marketing managers being seen accessing PHI when it was done in the academic offices. The files were left for the clinical

marketing managers in boxes, envelopes, filing cabinets, or in other prearranged places where the clinical marketing managers knew to look.

185. Even the smaller, community-based hospitals allowed the MedImmune's CMMs access to PHI, even though there were no academic offices where the files of PHI could be left for and/or retrieved by the CMMs.

186. The hospitals in Pennsylvania from which MedImmune obtained PHI for tracking purposes included Children's Hospital Philadelphia, UPMC Pittsburg, Pinnacle Hospital, Lancaster General, and St. Joseph Hospital. There were particular hospitals with high numbers of premature babies covered by Medicaid in the territory that MM-PA/NJ managed, including Children's Hospital Philadelphia, St. Christopher's Hospital and Lankenau Medical Center.

187. The PHI made available to the CMMs by the NICU and PICU staff were most often discharge forms, which contained the patients' names, dates of births, gestational ages, insurance coverage details, the names of the pediatricians to whom the babies were discharged, and any notes from the hospital staff. The MedImmune CMMs obtained discharge forms for the patients and faxed these forms to the BSSs, who then tracked the babies in conjunction with staff from the pediatricians' offices.

188. The CMMs generally knew the geographic area where each pediatrician operated, and which of the BSSs covered each area. As such, the CMMs knew which BSSs to fax the discharge forms, based on the pediatricians to whom the babies were discharged. This process of faxing discharge forms to the BSSs was referred to as the "handoff policy" internally at MedImmune during MM-PA/NJ's latter years of employment. Once the biotech sales specialists received the discharge forms, they were tasked with ensuring that each baby identified in a

discharge form was accounted for among the charts and logs maintained at the pediatrician offices on which they called.

Lunches and Paid Speakers

189. There were various lunches that MedImmune sponsored for the doctors and their staff. One such event was the "season kick off lunch" that the MedImmune BSSs had at the start of each RSV season with the doctors and their staff in each office. Receptionists were also included in these meetings. The lunches also afforded the biotech sales specialists more time in the doctors' offices, and doing so translated to more time to review patient charts.

190. There was a per-person spend limit in place for the lunches that MedImmune sponsored at the doctors' offices. However, the MedImmune representatives circumvented the limit by adding names of attendees who did not attend the events to the sign in sheets for the lunches to make it appear that they adhered to the per-person spend limits. Sometimes, fictitious names, such as Homer Simpson or Charlie Brown, were used. There was no requirement at MedImmune that the area business manager or other staff verify attendance.

191. MedImmune also paid some of its highest prescribing doctors as speakers for the Synagis product. Prescribing patterns were available to the managers from third party data MedImmune procured from IMS.

192. Some other speakers were selected due to their ability to influence their peers to prescribe Synagis.

193. Regional Director Jerry O'Malley sometimes questioned why some speakers were on the roster when they were known to only prescribe within the AAP eligibility guidelines.

O'Malley encouraged that speakers who "think outside of the box" and did not limit their prescribing habits by adhering to the eligibility guidelines be added to the speaker roster.

MedImmune Presented A False Appearance of Propriety to Obscure Noncompliant Improper Sales Practices

194. MM-PA/NJ concluded that MedImmune's internal processes were "corrupt" and designed to disguise improper sales tactics. For example, in the process of creating the new business template, MM-PA/NJ worked closely with a member of the MedImmune compliance team by the name of Jim Massey. Massey was well aware that MedImmune's sales practices concerning Synagis were non-complaint and were centered on accessing patient data to identify and track babies who were potentially eligible for Synagis. Massey was brought into the development of the new business plan template to suggest wording that could be used to describe some of the sales processes in a manner that made it appear that the practices were compliant when they were not.

195. MM-PA/NJ that MedImmune's 3-person compliance team was very small for a company of its size.

196. MM-PA/NJ explained that the business plan template had a drop down menu that had three or four reasons a manager could select to indicate why a particular sales goal was not met. In working with Massey, MM-PA/NJ ultimately included one such selection in the drop down menu that read something along the lines of, "Born out of season." This selection was used as a reason to explain why a baby who had been tracked ultimately did not end up being dosed. However, this selection was often used to cover up the real reason that led to the baby not being dosed, such as the baby not satisfying guidelines.

197. MM-PA/NJ had a sales call with his sales staff every Monday. During these meetings, he regularly discussed any changes that were announced by O'Malley during the weekly conference calls that took place on Friday. On one of these Friday conference calls in or around 2009, O'Malley announced that the term "patient tracking" could no longer be used, and should be replaced with the more palatable term "patient identification." MM-PA/NJ explained there was some loophole in the regulatory requirements that made patient identification legal in some aspects. Therefore, MedImmune management had determined that the company was best served and most protected from anyone discovering the non-compliant activity at the company if the term "patient identification" was used in lieu of "patient tracking."

198. However, the actual processes of identifying babies being discharged by the hospitals and tracking these patients at the pediatricians' offices did not change.

199. Similarly, O'Malley instructed his area business managers to refer to the discharge forms as "hand off forms" going forward. Another change that occurred related to how the biotech sales specialists accessed patient charts at the pediatricians' offices. MM-PA/NJ stated management directed that mandated the biotech sales specialists were no longer allowed to pull patients charts on their own for review. However, this did not stop the sales specialists from accessing charts. Rather than pulling the charts, the sales specialists just arranged for the doctors' staff to pull the files and leave them in folders on desks in the offices where the sales specialists could access and review them. Management, of course, -- which was pushing for greater tracking by the BSSs -- knew that the directive was toothless and would not change behaviors on the ground.

200. When BSSs were barred from using the Synagis stickers on patient charts they reviewed, the representatives responded by placing the Synagis package insert in the files of patients who they believed were likely eligible for dosing of the product. And, when that practice was frowned upon, the sales specialists paper-clipped the package inserts to the outside of the files to signify likely eligibility for Synagis to the doctors and/or their office staff members.

Florida

201. BSS-FL (2006-2009) worked with a Caremark representative on getting referral forms approved and, in doing so, discussed babies' names and dates of birth with the Caremark representative.

202. BSS-FL used Synagis binders to track patients, which were a means for her and the office staff to have all necessary information, including PHI, in one central location. BSS-FL noted that some doctors did not allow for the Synagis binders and/or for BSS-FL to access patient data, but BSS-FL was still able to track babies seen by these doctors by using descriptors, such as the county the baby lived in or the color of the baby's hair.

Oregon

203. BSS-OR, an Oregon-based biotech sales specialist from 2001 to approximately 2009, covered Legacy Emanuel Hospital, in Portland, which services a population including Medicaid patients. In this role, she promoted Synagis in Oregon. The Synagis coordinator at Legacy Emanuel Hospital regularly faxed PHI to BSS-OR, which she then used for the purpose of tracking babies. During this time, she witnessed off-label use of Synagis, including babies with Down Syndrome or cystic fibrosis receiving Synagis shots based on doctors' recommendations.

New York

204. MedImmune employees infiltrated New York hospital NICUs without having any written business associate privacy agreement ("BAAs") with these hospitals or parental consent to obtain PHI of former or current NICU babies, which provided valuable leads to solicit parents of high-risk infants. State Cmpt. ¶8.

205. MedImmune tried to obtain lead information and prescriptions from NICU prescribers for former NICU patients even if they had no current relationship with the baby.

206. NYAG's allegations are consistent with facts provided from across the country from Relator's investigation. For example, on October 4, 2011, Witness 1 gave birth to her son six weeks premature at St. John's Riverside Hospital in Yonkers, New York. His birth weight was low at only 4 lbs, and he was kept in the NICU.

207. A neonatologist explained to Witness 1 that her son was at risk of contracting RSV. Before being discharged, Witness 1 received various documents regarding RSV. These documents include: (i) a subscription form titled "Early Delivery" which solicits authorization for MedImmune and its contracted partners (sponsors of this program) to contact the parents about RSV and related products and services; (ii) a magazine for parents of premature babies titled "Early Delivery" provided by MedImmune and the Association of Women's Health, Obstetric and Neonatal Nurses ("If your baby was born prematurely, ask his health care provider about medication that helps prevent RSV disease."); (iii) a newsletter for parents of premature babies also titled "Early Delivery" provided by MedImmune ("Ask your baby's doctor about how to help protect your newborn from RSV"); (iv) RSV (Respiratory Syncytial Virus) – A Guide for

Parents; and (v) a chart titled "Your Growing Baby" in which the parents can fill in the dates of checkup and track the baby's growth, also provided by MedImmune.[4]

208. Witness 1 never signed the Early Delivery subscription form, nor did she provide her phone number or contact information on the form as is requested; the blank form is attached.

209. Nevertheless, subsequent to her son's discharge, on October 17, 2011, Witness 1 received a phone call at home from a MedImmune representative, who recommended that Witness 1's son receive Synagis shots in light of the fact that he was born prematurely.

210. Shortly thereafter, Witness 1 received a phone call from her son's pediatrician, stating that Synagis arrived at the pediatrician's office to be administered to her son. Witness 1's son received five monthly doses of Synagis.

211. The following year in September or early October 2012, Witness 1 received another call from a MedImmune representative. The representative wanted to confirm that there was no change regarding Witness 1's son, including the identity of the pediatrician and his office address. The MedImmune representative asked, "Can we get your son started on another round of Synagis?" She also asked whether Witness 1 had a new child.

212. Witness 1 also found out that a pharmacy had contacted her son's pediatrician to inquire about Synagis for him.

213. MedImmune's primary New York area business manager, designated Medi Manager 1, knew that members of his sales team took information from NICU logbooks

[4] Notably, the MedImmune brochure states: "Your baby is most at risk of getting RSV during flu season (October through May)." Synagis' FDA-approved label states, "[i]n the northern hemisphere, the RSV season typically commences in November and lasts through April."

including taking "down patient names for every baby born 35 weeks or less gestational age." State Cmpt., ¶101. He also knew that MedImmune would "convey the information over to a pharmacy, and in most cases it was Trinity because Trinity had a lion's share of NICU coverage in the [New York] area." *Id.*

214. CMM 1 and other MedImmune sales representatives obtained baby leads or referrals of patients in at least the following hospitals: Brookdale Hospital, Coney Island Hospital, Jamaica Hospital Medical Center, Kings County Hospital, The Brooklyn Hospital Center, Woodhull Medical Center, New York Methodist Hospital, SUNY Downstate Medical Center, and Long Island College Hospital - SUNY Downstate. *Id.*, ¶107.

215. For example, on July 2, 2007, CMM 1 wrote to a New York hospital NICU physician describing his typical process for gathering Synagis leads at a NICU. *Id.*, ¶104. To facilitate the process of identifying babies who may be in need of Synagis, CMM 1 stated that "I was hoping we could meet at the hospital and go through the logbook. I'm happy to sit (out of everyone's way) and compile the data myself as I do in many other hospitals…" (Emphasis added). *Id.*

216. MedImmune's tactics were highly successful in generating Synagis prescriptions. The New York investigation found that one-half of the sample of leads obtained resulted in Synagis prescriptions paid for by Medicaid, which financially benefitted MedImmune and Trinity. Other specialty pharmacy/health providers would also have benefited from MedImmune's leads and assistance.

C. Relator's Knowledge of Improper NICU Access

217. Bellevue is a large public hospital and a member hospital of the New York City

Health and Hospitals Corporation ("HHC"). Bellevue is located in lower Manhattan. In 2008, Bellevue handled more than 470,000 clinical visits, including more than 2,000 births. Bellevue's low-income patients often apply for and receive Medicaid assistance.

218. In 2006, Relator was contacted by Dr. Yang Kim, the director of Bellevue's NICU, who indicated that the Bellevue NICU was going to start to use a pharmacy, known as Trinity. Trinity and MedImmune were promoting a comprehensive follow-up program and Dr. Kim recommended that outpatient physicians now refer patients to Trinity. As evidenced in a September 17, 2011 email from Julia Chang-Lin to Relator titled "Meeting at Bellevue re: Synagis," Dr. Yang Kim admitted she allowed Trinity "access to the discharges so that no one would be lost to follow-up."

219. In an email dated July 2, 2007, CMM 1 wrote to a New York hospital NICU physician describing his collaboration with Trinity and how he would use patient information and share it with the pharmacy. This included, "making contact with the [baby's] family to verify all info. as well as send them educational/premium items *i.e.*, soap in order to prevent the spread of RSV, preemie magazine. Trinity then makes regular follow up calls/mailers until the season begins." State Cmpt., ¶104.

220. CMM 1 further explained that "[t]he real motivation behind this program is simple. Medicaid patients tend to have inconsistent living conditions as you know. Typically, [Trinity's Synagis Director] will receive a list from a NICU in August and several patients (about 50%) will have non working/disconnected phone numbers, wrong address, different names etc. and unfortunately, go without therapy. Our efforts are geared toward contacting these patients before these changes take place. All of that being said, I was hoping we could meet at the

hospital and go through the logbook. I'm happy to sit (out of everyone's way) and compile the data myself as I do in many other hospitals." (emphasis added). *Id.*

221. The "Synagis People," as they were called by hospital staff, promoted their pre-outpatient prescription collaboration. *Id.*, ¶4. For example, CMM 1 and Trinity's Synagis Director gave a joint presentation titled, "Kings County Synagis Program, 2007-2008 RSV Season" to the Kings County Hospital NICU. *Id.*, ¶132. Their joint document included information under the heading, "Communication/Data Management" that states, "Unable to Locate, Trinity/MedImmune will communicate with Kings NICU." *Id.* Without detailing any separation of roles between the drug manufacturer and the pharmacy, the "Synagis People" would then follow-up with NICU staff and potential prescribers to obtain babies' missing personal and demographic information as leads to try to obtain Synagis prescriptions. *Id.*

222. Relator reminded Dr. Kim that the Pink Clinic followed most of the high risk infants who qualify for the drug after discharge and was frequently consulted on those who are followed by other providers regarding Synagis. The PINK Clinic's social workers tracked patients and ensured continuing care. In sum, Relator and her colleagues saw no need for the program.

223. Trinity was not the only specialty pharmacy that accessed the NICU logs. On September 25, 2010, at 9:41am, Angelita ("Angie") Lopez of Americare Pharmaceutical Services sent an email titled "SYNAGIS 2010 – BELLEVUE – POSSIBLE" to Relator, stating, "Please review the list I received from the NICU. …. Please let me know when I will be able to drop off the new referral for synagis and nursing forms for home care patients." Lopez attached a spreadsheet titled "Synagis 2010 – Bellevue – Possible," which contains numerous babies' names

and contact information. Shortly thereafter, at 10:46am, Lopez sent another email to Relator and Julia Chang-Lin titled "Synagis" with a list of babies, stating "Below is a list of patients that where [sic] seen in the NICU. Please let me know of [sic] they are being seen by your clinic. I also have new Nursing and Synagis referral forms. Please let me know when will it be possible to drop them off to get the season started for your patients." Relator produced these documents to the NYAG and USAO.

D. Trinity Pushes for Broad Synagis Usage

224. As a physician following many pre-term infants after hospital discharge, the Relator was often asked to renew the medication and/or home nursing care. However, it seemed that many infants referred by the NICU did not meet FDA-indicated criteria for Synagis. Relator was consulted by several pediatric attending and resident physicians, and nurse practitioners who received calls while covering the pediatric clinic from pharmacists and homecare agencies, like Trinity, requesting orders or refills for Synagis. Relator was also approached by parents who had been called by Trinity about their baby's need for Synagis. Parents whose babies did not meet the medical criteria for Synagis received calls at home from Trinity staff encouraging them to ask their doctor to prescribe Synagis.

225. As documented in a patient chart by Julia Chang-Lin, MD on October 21, 2008, the mother of the patient asked Dr. Chang-Lin whether the baby needed more Synagis. The mother had been contacted by Trinity Home Care. Dr. Chang-Lin explained to the mother that the baby would not meet the AAP guidelines for needing Synagis. Relator produced this document to the NYAG and USAO.

226. As documented in a patient chart by Relator on December 3, 2008, the mother of the patient reported that Alexandra from Trinity Homecare called her to recommend Synagis for the patient. The mother thought this was someone from Bellevue NICU. Relator explained the risks and benefits to the mother, who agreed that Synagis was not indicated for the patient who was a 6 ½ months old former 33-week pre-term boy. Relator produced this document to the NYAG and USAO.

227. In a hand-written note, Relator's colleague listed three patients, and stated, "These are the [patients] Trinity was calling about." Relator produced this document to the NYAG and USAO.

228. From these phone calls and conversations, it became apparent that PHI was used to contact parents of babies discharged from the NICU, for the purpose of urging Synagis or more Synagis for their infants.

229. During conversations with Angie Lopez, Relator was advised that PHI was being misappropriated from NICU logs at other hospitals, including Einstein (Bronx County) and Sound Shore (Westchester County), as a matter of course.

230. Relator advised the NYAG during Relator's investigation and in follow-up communications that she was told there was also unauthorized access to NICU logbooks for PHI at hospitals in Queens and Brooklyn.

231. Relator observed that, every season, someone would come to Bellevue with a large binder of materials from MedImmune, referral forms, and patient brochures, demonstrating the coordination between MedImmune and Trinity. At that time, Relator believed such coordination was inappropriate and violated HIPAA.

232. Anita Smith was an Executive Clinical Marketing Manager at MedImmune, and a MedImmune representative to Bellevue. She offered to take the doctors out to lunch to present relevant information. Relator declined the lunch invitation and instead accepted the information only.

233. Trinity's conduct became apparent at Bellevue because of the Pink Clinic's unique high-risk follow-up program in outpatient pediatrics. In most facilities, high-risk infants are followed in general pediatrics by various providers.

234. On or about October 1, 2008, Relator also became aware that Synagis and home nursing care were ordered by Trinity under her name and medical license for an infant patient (Baby #1), who Relator had never treated. Baby #1 had been discharged from the Bellevue NICU but never been treated by Relator. Upon receipt of a prescription for Baby #1 with her license number on it, Relator pulled Baby #1's file and determined the baby was not medically eligible for Synagis. Relator reported the theft of her license and the inappropriate prescription to the Bellevue NICU and on November 24, 2008, Relator met with E. Christopher Roberson, Bellevue Network Compliance and Privacy Officer (the "Compliance Officer"). Relator also consulted her supervisor, Dr. Arthur Fierman, about what Relator should do about the false and unauthorized use of her medical license. [5]

235. During her investigation, Relator learned of several other cases, in addition to infant patient Baby #1, where Synagis was ordered for patients who did not meet the FDA criteria for Synagis, including:

[5] In an email dated September 17, 2011, Relator was informed that other unlawful uses of medical licenses had occurred. Dr. Chang-Lin stated that "Trinity used [Dr. Yang Kim's] name and license number under verbal orders for ongoing Synagis orders which [Dr. Kim] did not know about."

(a) infant patient Baby #2, who was born at 35 weeks' gestation; the pediatric resident consulted with me and spoke with Baby #2's mother, and we were able to discontinue the prescription of Synagis;

(b) infant patient Baby #3, who was discharged from the NICU but then contacted directly by Trinity at her home to arrange an inappropriate prescription of Synagis; and

(c) infant patient Baby #4, was prescribed Synagis but had no clinical indications for such treatment.

236. On April 20, 2009, Relator filed her initial complaint under seal. Relator alleged (at ¶64): "Trinity obtained access to hospital logbooks or surreptitiously obtained patient records located in the NICU at Bellevue in violation of HIPAA. With access to NICU's patient records, Trinity was then able to contact the parents of NICU patients subsequent to their child's discharge from the hospital in an effort to secure them as clients and to deliver home care services, including the administration of Synagis, to those patients." Relator and counsel met with the NYAG regarding Relator's investigation.

237. Relator later learned that Bellevue placed some restrictions on Trinity, including that outpatient physicians would be solely responsible for ordering this drug for eligible patients and that the NICU would order the drug for hospitalized patients only.

E. MedImmune Used Its Influence to Set-Up Trinity as Bellevue's Synagis Provider

238. Upon information and belief, prior to Trinity's introduction at Bellevue, MedImmune and Trinity had already been conspiring and collaborating at other hospitals to misappropriate and exchange confidential patient information to increase Synagis orders.

239. In April 2008, Trinity hired a former MedImmune employee as an account manager ("Trinity Account Manager"), at the recommendation of MedImmune CMM 3.

Thereafter, Trinity's new Account Manager attended a meeting at Bellevue Hospital Center ("BHC") arranged by and attended by CMM 3, BHC neonatologist and BHC NICU Director ("BHC NICU Director") Dr. Yang Kim, and the Director of Social Work at BHC. State Cmpt., ¶142.

240. The purpose of the meeting was to discuss a proposed Synagis tracking program by Trinity that would follow former patients of the NICU. *Id.*, ¶143. Some of these patients were being seen by the outpatient clinic and others were not. *Id.* These babies had not received a prescription for Synagis before they were discharged from BHC. *Id.*

241. CMM 3 recommended Trinity to BHC for Synagis outpatient purposes. *Id.*, ¶144. Trinity's Account Manager stated that "this was a hospital that was targeted for me to work with. The MedImmune rep contacted me. I have a contact there. I have a relationship with the director; did I want to go in." *Id.*

242. Trinity's Account Manager further stated, "Everything I did mostly with this account for the time that I worked with them was through [CMM 3]." *Id.* This introduction and ongoing assistance by MedImmune presented an opportunity for Trinity to increase its Medicaid reimbursement for Synagis and for MedImmune to make sales. *Id.*

243. Trinity's Account Manager understood the power of MedImmune's assistance and CMM 3 was the "mechanism" by which Trinity's Account Manager gained access to the BHC NICU for outpatient purposes. *Id.* Trinity's Account Manager stated that, "[CMM 3] was the one who brought me into that NICU…" *Id.*

244. Trinity's Account Manager also generally stated that, "Often times, it was the MedImmune rep who would have the contact [at the NICU], and would say, hello, this is

[Trinity's Account Manager], she will assist you in identifying those babies at high risk for Synagis prophylaxis." *Id.*, ¶145.

245. Trinity's Account Manager obtained information about babies from visiting the BHC NICU. *Id.*, ¶146. Trinity's Account Manager stated her usual "vehicle" for getting in touch with the BHC NICU Director was through the MedImmune rep. *Id.*

246. MedImmune's recommendation that Trinity be the pharmacy to provide BHC's outpatients with Synagis resulted in at least one baby receiving Synagis without a prescription from the prescriber identified on the Medicaid claims. *Id.*, ¶149. In October and November of 2008, Trinity presented claims to the Medicaid program identifying Relator as the prescriber, even though the Relator had not prescribed Synagis for the baby. *Id.* After Relator learned about the unauthorized use of her name by Trinity, she reported the incident to BHC. *Id.*

247. MedImmune also became aware of the unauthorized use of the Relator's name and Trinity provided MedImmune with information identifying the baby. *Id.*, ¶150. CMM 3 approached Trinity's Account Manager and Trinity's Account Manager stated that, "[CMM 3] is the one who asked me about this child… maybe I felt she should be the first to get an answer." *Id.*

F. MedImmune and Trinity Are Barred From Hospital NICUs; and MedImmune Eliminates the CMM Hospital Sales Position and Orders Relevant Documents Destroyed Nationwide

248. As documented in a hand-written note dated January 29, 2009, Trinity was banned from Bellevue and stricter vendor rules were introduced. The note states that Trinity was reviewing NICU logbook and staff were getting trained. Relator produced her notes to the NYAG and USAO.

249. Following Relator's formal complaint, a letter dated March 3, 2009, from BHC's Director of Network Contracts to the Visiting Nurse Service ("VNS") that Trinity had referred the baby to (which copied Trinity), stated, "Please be advised that Trinity Representatives should not be on Bellevue Hospital Center Premises except in instances coordinated by the Bellevue Hospital Center Social Work Department. And even in those instances, Trinity Representatives should not be acquiring personal and confidential patient information. These activities must cease immediately. Furthermore, Trinity Representatives shall not use any information gathered while on Bellevue Hospital Premises for any marketing purposes whatsoever." State Cmpt., ¶151.

250. In summer 2009, CMM 1 was barred from retrieving baby information from the NICU logbooks at KCH. *Id.*, ¶152. His supervisor, Medi Manager 1, conceded to the NYAG that he knew that the KCH NICU Director had "put a stop to it." *Id.*

251. On October 13, 2009, CMM 1 emailed the KCH NICU Director in an effort to regain access to the KCH NICU. *Id.*, ¶1153. CMM 1 stated, "I think it would be great for us to have a very candid conversation regarding what has gone on and what Kings County will do moving forward." *Id.* CMM 1 admitted that he had independently taken information from the KCH logbooks. *Id.* The email stated, "First, my fear is that I give the wrong impression of myself in the hospital due to the fact that I am a sales representative. ... Another concern I have is logistics. That is why I urge you to allow me in to the process… We haven't tracked patients in the NICU this summer as well, which makes patients harder to find, as this is a very transient community…" *Id.*

252. Without access to the NICU, MedImmune was no longer able to access leads or to

directly contact parents of babies in the NICU. *Id.* Nor could it forward their information to Trinity or other pharmacies for follow-up. *Id.*

253. On December 5, 2010, CMM 1 sent an email to Medi Manager 1 and MedImmune's Northeast Senior Government Affairs Manager, referencing a New York governmental investigation concerning Synagis, stating, "Apparently, one of the attending neonatologists was questioned by NY Medicaid for a lengthy session, so I'm told. I don't have the details but I do know that Kings is a huge NICU and haven't properly kicked off their Synagis season, at least partly due to this issue." *Id.*, ¶154.

254. MedImmune long recognized that the inability to access NICU baby identities would have an adverse impact on the Company's revenues and growth prospects. For example, a June 2009, Medi Manager 1 authored PowerPoint, "ID103 Manhattan-Long Island 2009-2010 Business Plan," contained a section titled "Puts & Takes": Synagis. "Puts" is defined as "opportunities" and "Takes" is defined as "threats." In the Takes column, Medi Manager 1 identified his managerial concern, "NICU's restricting CMM/distributor access to birthing Log Book → decrease in patient ID expected." (Emphasis added). *Id.*, ¶165.

G. MedImmune Supervisors Were Aware of and Encouraged the Aggressive Misappropriation and Sharing of Patient Data

255. MedImmune account managers were well aware of, encouraged and rewarded sales representatives who obtained PHI of potential Synagis candidates in order to drive up revenues. For example, in an October 4, 2006 email from CMM 1 to both his regional and national account managers ("Medi Managers"), CMM 1 lauded Trinity's conduct, stating that MedImmune "need[s] [its] nationals to have a fraction of that ambition" in following up on patient information obtained by the sales force in order to generate revenues from Synagis. *Id.*,

¶88. On February 6, 2007, a former MedImmune BSS, designated "BSS 4," emailed her regional supervisor, Medi Manager 1, highlights from her week. The email states, "I had a lunch meeting with Brookdale @ New Lots to review their referrals. ... We were able to capture three babies and get their drug shipped to the office. As mentioned before I implemented my new binder and we wrote down each baby and the date dose. In addition, any subsequent referrals that go to Trinity will be copied and placed in my binder for tracking purposes." *Id.*, ¶159.

256. On February 8, 2007, Medi Manager 1 responded by complementing BSS 4 for "taking more accountability at New Lots." *Id.*, ¶160.

257. In an email titled, "NICU Update," dated October 9, 2007, from CMM 1 to Medi Manager 1 and his superior, Medi Manager 5, CMM 1 boasted about his access to and use of PHI that he provided to Trinity. *Id.*, ¶161. He stated that "[n]ow I do 100% of the tracking and the info flows from the NICU to Me to Trinity and then back to me again so I can note patient status as well as dig deeper for better quality of info. As it stands, our growth is right in front of us within our books." *Id.*

258. Medi Manager 1 responded the same day in glowing terms, "This is absolutely terrific work!!! When I look at the amount of control and accountability you have taken on with your accounts I am very impressed! Keep this same level of intensity throughout the entire season and success will be yours!" *Id.*, ¶162.

259. Medi Manager 5 echoed Medi Manager 1's praise stating, "...Thanks again for the efforts! I know that this work takes extraordinary effort and finesse." *Id.*, ¶163. Medi Manager 5 further responded to CMM 1's email, "Thanks for the perspective. Congratulations and great job in taking control of the process this summer." *Id.*

260. Similarly, on November 22, 2008, Medi Manager 1 emailed CMM 1. The email stated "[CMM 1]: Thanks for a very productive day at Kings County Hospital. You truly performed some true hospital salesmanship. Your NICU protocol produced another 21 babies identified for Synagis administration in the last (3 weeks) 126 to date…" *Id.*, ¶164.

261. In May 2007, MedImmune and Trinity were scheduled to meet at Trinity's College Point Office to discuss, among other topics, early referrals. *Id.*, ¶113. A MedImmune document, authored by Medi Manager 1, referenced a "Trinity SDN Partnership Meeting" for May 30, 2007. "Points for Discussion" included, "Early Referrals" including "Excel Spreadsheets ([CMM 1]) and Excel Spreadsheet Data Merge with Referral Forms…" Further, Compliance/ Communication included, "Timely Information Share with MedImmune Sales Personnel." *Id.*

H. MedImmune Teams Up with Trinity to Increase Synagis Sales

262. MedImmune's sales organization openly acknowledged that Trinity controlled the New York market for the distribution of Synagis, and sought to maximize sales by using Trinity's position to jointly access PHI and track babies. For example, on October 4, 2006, CMM 1 e-mailed the Executive Manager of National Accounts (designated "Medi Manager 2"), his Area Business (Sales) Manager (designated "Medi Manager 1"), and other MedImmune employees, observing that "Trinity is a small pharmacy who handles approximately 80% of [Synagis] business" in Brooklyn, the Bronx, and Manhattan. He admired Trinity's strength in "getting a little information and then digging to find the rest." *Id.*, ¶88.

263. In another email, dated March 31, 2009, titled, "NY Medicaid data," forwarded from another Regional Account Manager, (designated "Medi Manager 3") to MedImmune Vice

President of Managed Care Markets, (designated "Medi Manager 4"), Medi Manager 3 attached a MedImmune slide deck titled, "New York Medicaid PA Analysis." *Id.*, ¶89. MedImmune acknowledged therein that for the 2008-2009 Synagis season "Walgreens/Option Care [formerly Trinity] has 64% of the NY Medicaid business; there are only 2 other of 56 distributors with >10%: Regioncare (12.3%) and Omnicare (10.5%)". *Id.*

264. In a February 8, 2007 email, from BSS 1 to her supervisor, Medi Manager 1, and other colleagues, including CMM 1, MedImmune described a component of its plan to work with Trinity in obtaining additional Synagis business. *Id.*, ¶102. The email titled, "Notes from Biz Unit Meeting," states, "Here are the notes that I took on Tuesday regarding our plan of action for the remainder of the season: We have two goals at this point 1) Recover lost patients 2) Activate new patients… Breaking it down into hospitals… The next step is confirming these numbers with Trinity. [CMM 1] is going to try to obtain the lists from Trinity and give them to us. We are hopefully going to get the lists/referrals from all hospitals because there may be some overlapping between territories. Once we have this information we are going to do the following: Take referrals to WIC coordinators to see if we can locate babies[,] [a]ppeal to them on clinical grounds[,] [m]aybe take [ ] with us…" *Id.*

265. On February 12, 2007, CMM 1 followed-up and wrote an email titled "Lists of Inactives" to Trinity's former RSV Program Manager/Account Executive and later the Director of Business Development ("Trinity's Synagis Director"), referencing babies for whom Trinity was not dispensing Synagis. *Id.*, ¶103. The email states:

> "I wanted to send you a reminder that we need to get those lists together. You have told me it's easy and I believe you. So please, pretty please with sugar on top, could you please bring the lists for SUNY, Kings, Brookdale, Wyckoff, and Woodhull. I will have B.A.

> agreements in tow with me this week. And if you are still uncomfortable with me handling this info I will gladly escort you to any and all facilities to get these in the right hands. If you do not think this is a worthy pursuit please tell me and just let me then run with the info. This as well as April dosing are of my top priorities right now. This would mean a lot to me." *Id.*

266. In sum, CMM 1 would take baby names from the logbooks, transfer the information to spreadsheets, and then send that information to Trinity for follow-up. Using the information on CMM 1's lists of leads, Trinity's Synagis Director and employees contacted the babies' families and prescribers to try to obtain Synagis prescriptions for those babies.

267. For example, on July 16, 2008, CMM 1 sent an email to Trinity's Synagis Director (and cc'd "Trinity's Synagis Coordinator") titled, "New Tracking and New Contact Info. (Coney Island, LICH, Woodhull, Kings, SUNY)." *Id.*, ¶108. The email stated, "Hey guys, here are some attachments with new tracking and the other is updated info from SUNY and Kings. [Trinity Synagis Director], could you go ahead and send me the new Kings tracking when you have a moment? And I counted about 12-14 patients from our last round at Methodist. Can you verify that number? Oh, and the updates are in yellow when you scroll to the left. Let me know if you have any questions. Thanks! [CMM 1]." *Id.* The information provided by MedImmune and sent to Trinity included: baby name, date of birth, gender, record number, name of hospital baby was treated in, guardian/parent names, addresses, and telephone contact information. *Id.*

268. On August 14, 2008, CMM 1 emailed Trinity's Synagis Coordinator and cc'd Trinity's Synagis Director attaching names of patients from SUNY Downstate and Kings County Hospital ("KCH") and asked them to check, "that I picked up where [Trinity's Synagis Director] left off at Kings." This referenced CMM 1 retrieving names of babies from the KCH NICU logbook. *Id.*, ¶109.

269. Similarly, in an email dated August 17, 2008, titled, "new Jamaica," CMM 1 sent to Trinity's Synagis Coordinator and cc'd Trinity's Synagis Director; he attached a spreadsheet containing baby names he obtained from Jamaica Hospital NICU tracking, which he sent to Trinity for follow-up. *Id.*, ¶110. The email stated, "Here are the new Jamaica patients I tracked on Friday. Talk soon!" *Id.*

270. MedImmune encouraged the sharing of leads with Trinity. A document prepared for a meeting between MedImmune and Trinity titled, "MedImmune/Trinity Partnership Meeting Monday April 23, 2007 College Point, NY," discussed, "Daily Email Reports… Referrals/Leads" and further referenced the following, "Patient Identification Program (Tracking)…Share all referral data." *Id.*, ¶112.

271. On September 13, 2008, CMM 1 wrote an email to Trinity's Synagis Director titled, "New Methodist and LICH patients." *Id.*, ¶115. The email also contained a request. CMM 1 asked, "…Could you send me a copy of the Trinity form as a word document so I can mail merge them and send you spreadsheets as well as the spreadsheets? I am doing a ton of tracking next week and I hope the mail merge thing could make things easier for you…" *Id.*

272. That same day, Trinity's Synagis Director emailed CMM 1 "the internal NICU Trinity referral form." *Id.*, ¶116. Trinity's Synagis Director emailed the July 2007 version which required information as to the identity of the referral/physician information and the identity and phone number of the person who made the referral. *Id.*

273. Later, that same day, CMM 1 stated in an email to Trinity's Synagis Director, "I can mail merge onto Trinity's form but doesn't save so I'll be happy to walk you through it." *Id.*, ¶117.

274. Upon receiving leads from MedImmune and others, Trinity typically sent form letters to potential prescribers suggesting that a baby qualified for Synagis without disclosing that in some cases, (i) an unlicensed medical professional, a MedImmune employee, had identified information about a baby and provided that information to Trinity or (ii) had determined to give referrals from providers without prescriptions selectively to Trinity.

275. MedImmune's NICU tracking and providing names and PHI to Trinity knowingly caused the presentment of false claims to Medicaid, which resulted in increased sales of Synagis ultimately paid for from public funds to MedImmune.

276. According to ¶130 of the NYAG Complaint, MedImmune management, including Medi/AstaZeneca's Compliance Director, conceded that MedImmune should not have been providing PHI to a pharmacy, even if the parent/guardian "of these vulnerable babies would sign off and say, we agree that MedImmune may take our child's name… along with where we will be taking them for their pediatric visit, and hand it [the 4 Part form] from the NICU provider to the next caregiver."

277. Medi/AstraZeneca's Compliance Director admitted that, under the circumstances, it would be improper for a MedImmune employee to assist a pharmacy by providing it with the names of patient baby leads that it obtained at a NICU. Further, "the next caregiver" referenced in the form was not supposed to be a pharmacy without a prescription. (State Cmpt. ¶130).

I. MedImmune Provided Personnel Assistance and PHI to Increase Its Sales of Synagis

278. Medi Manager 5 also conceded that a MedImmune representative should not be working in conjunction with a pharmacy representative to obtain a lead and/or a referral for a prescription, and conceded, "such conduct should not occur." State Cmpt., ¶133.

279. A Trinity employee described MedImmune's assistance in trying to obtain Synagis prescriptions for Trinity as, "[y]ou let them [MedImmune,] know who the baby is. Who the doctor is. Then they go in and I guess talk to the doctor and let them know why Trinity is trying to reach them." *Id.*, ¶134.

280. Medi Manager 1 was aware of occasions when MedImmune helped collect additional information about the baby that would allow the pharmacy to contact the patient. *Id.*, ¶135. In pursuit of an opportunity for MedImmune to profit, CMM 1 went so far as to improperly gather PHI by going to hospital birth certificate offices to obtain current phone numbers and addresses of babies that CMM 1 then provided to Trinity. *Id.* Medi Manager 1 knew that CMM 1 was doing this to turn leads into referrals. *Id.* He would "use the birth certificate office as a vehicle to get current phone numbers and home address and feed that information back to Trinity for them to contact the parent." *Id.*

281. Medi/Astra Zeneca's Compliance Director admitted to the State: "Our employees should never have had access to [birth certificate information or records]." *Id.*, ¶136. As a result of such fishing expeditions, Trinity could contact the parents/guardians of those babies or have the parents/guardians contact physicians to try to turn MedImmune leads into Synagis prescriptions. *Id.*

282. MedImmune also provided personnel assistance to Trinity, some of which was documented in Trinity's CPR and clinical notes, internal electronic record keeping systems implemented by Trinity to maintain data including that of potential Synagis customers as well as Trinity's active Synagis customers. *Id.*, ¶137. These notes documented that MedImmune employees provided information to Trinity about a baby's medical eligibility regarding recent

and future dosing for current Synagis customers, as well as providing Medicaid ID numbers, dates of birth, and addresses. *Id.* This was done so that Trinity could allegedly dispense Synagis to babies and present claims to Medicaid. *Id.*

283. For example, the following notes represent how MedImmune provided remuneration to Trinity via personnel assistance:

1) 03/21/07, "As per [BSS 1] from MedImmune, Mom has re-applied for caid + should have card shortly; will meds ASAP". To be billed as caid pending as MD needs meds." Referring to (Baby 76, Ex. C1 to State Cmpt). *Id.*, ¶138.

2) 08/17/07, "Confirmed all info w/aunt (mom does not speak English); she will c/m/b w/caid #'s and name of PCP (new info. given to me by [CMM1])". Referring to (Baby 85, Ex. C2 to State Cmpt.). *Id.*

3) 02/19/08, "Rec'd caid # for twins from [BSS 2] at MedImmune 03/13/08, As per [BSS 2] at MedImmune, baby was dosed 02/23/08 (WT=9lbs)". Referring to (Baby 42, Ex. C1 to State Cmpt.). *Id.*

4) 04/14/09, "Rec'd new caid # from [BSS 3] (MedImmune)." Referring to (Baby 328, Ex. C1 to State Cmpt.). *Id.*

284. Other notes demonstrate that MedImmune provided personal information to Trinity about babies who had already received Synagis injections on an outpatient basis, at home, and Trinity then used this information to refill another seasonal monthly dose of Synagis. *Id.*, ¶139.

285. MedImmune also arranged for Trinity's services, such as for Synagis to be delivered often to a medical facility, as it was faster than delivering it to the baby's home. *Id.*,

¶140. For example, the following CPR notes represent how MedImmune provided remuneration to Trinity by arranging for services:

1) 10/10/06, "As per Ida at MD office mom wants homecare; however, as per [Medi employee 1], Dr. Tapia wants MD office del (it is quicker to get meds)." Referring to (Baby 108, Ex. C1). *Id.*, ¶141.

2) 10/29/07, "As per [Medi employee 2] at MedImmune, of to del meds to MD office w/out contacting parents." Referring to (Baby 474, Ex. C1). *Id.*

3) 11/20/07, "[Medi employee 2] from MedImmune will have MD fax Rx today." Referring to (Baby 500, Ex. C1). *Id.*

4) 3/24/08, "As per [BSS 3] from MedImmune, Baby showed up in Dr. Chong-Gayle's office in Suffolk county w/the meds (del'ed to home in Nov; S/H/B given at BFCC); faxed referral form to new MD; will send new meds to MD office when new ref + Rx rec'd." Referring to (Baby 405, Ex. C2). *Id.*

5) 11/11/08, "As per [BSS 2] from MedImmune, ok to del meds to MD office." Referring to (Baby 451, Ex. C1). *Id.*

J. MedImmune Shuts Down Its CMM Program and then Destroys HIPAA-Protected Patient Information in Breach of Its Preservation Obligations Under CIAs

286. By April 14, 2011, with the aforementioned knowledge of a governmental investigation, MedImmune announced it was terminating its CMM program. *Id.*, ¶155.

287. MedImmune's compliance department determined to make sure its employees ceased obtaining access to and retaining PHI, and directed MedImmune employees to review their materials and records to destroy any paper and electronically saved PHI in their possession

by: shredding it, depositing it in confidential waste bins, or by completely electronically deleting it. *Id.*

288. MedImmune's directive violated the provisions of CIAs dated June 2003 and April 2010, requiring AstraZeneca to "maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with [the] CIA for six years (or longer if other required by law)," and the Company's Code of Conduct, which incorporated the document retention obligations.

289. Among others, BSS 3, BSS 4, and Medi Manager 1, executed the Certification of Destruction by April 30, 2011. *Id.*, ¶155.

290. On May 31, 2011, when CMM 3 departed from MedImmune, her secretary wiped-out her laptop hard drive and sent the laptop back to MedImmune. *Id.*, ¶147.

K. MedImmune Violated Its Obligations to Comply with Anti-Kickback Laws and Similar State Prohibitions

291. Despite its knowledge of compliance requirements, its legal obligations arising from the CIAs and its own corporate materials setting out forbidden practices, as alleged below, MedImmune knowingly allowed its employees to violate the law. MedImmune's conduct caused Trinity, Caremark, and other pharmacies to present false claims to the Medicaid program.

292. In AstraZeneca's Code of Conduct, which is applicable to MedImmune, employees were instructed "to comply with federal, state, local, and foreign laws and regulations in the places where they conduct business."

293. Code of Conduct specifically covered conduct implicating "The Anti-Kickback Act" it provided:

> The federal fraud and abuse laws cover all products or services that

> may be reimbursed, in whole or in part, by federal healthcare programs, such as Medicare or Medicaid. The fraud and abuse laws encompass various risk areas, most significantly kickbacks and other illegal remuneration. The federal anti-kickback statue makes it a criminal offense for any person to (a) knowingly and willfully (b) offer, pay, solicit, or receive (c) any remuneration (d) to induce (e) the purchasing or recommending of (f) any item or service that the federal government may pay for or purchase. This statute is extremely broad and covers a wide array of arrangements. Remuneration is considered anything of value: case, grants, consulting payments, free goods, entertainment, etc. (Emphasis added).
>
> ***
>
> In assessing the risk of an activity, the government does not consider the fact that a type of arrangement may be common in the industry as a defense to an alleged kickback. Violation of the statue may result in criminal prosecution, civil monetary penalties, and/or exclusion from participation in federal healthcare.
>
> In addition to the anti-kickback statue, there are other civil and criminal laws, such as the Federal Civil False Claims Act and the Federal False Statements Act, which may impose punishment for health care fraud and abuse. For example, the Federal Civil False Claims Act can result in significant financial liability if a party knowingly submits a false claim for reimbursement to a Federal health care agency, reports false pricing information, or engages in similar fraudulent activities. Many states, including Delaware, have enacted false claims laws that track the federal statute.

294. The Code of Conduct emphasized under a section titled "What is Expected of Each Employee" that AstraZeneca's compliance obligation were incorporated in the IA with the OIG. The section provides in relevant part: "all employees are expected to become familiar with and abide by the commitments AstraZeneca has made as part of the US Compliance Program and the Corporate Integrity Agreement with the OIG."

295. MedImmune knew that it was required to comply with HIPAA and anti-kickback laws with regard to Synagis, but it nevertheless acted in direct contravention of the law and its own policies and procedures. As noted in several iterations, of a document authored by

MedImmune's corporate compliance department titled, *MedImmune, Responsible Entrepreneurs: The Synagis Referral Process*, MedImmune knew that "educating and trouble- shooting around Synagis logistics and coverage issues raises real and serious risks if done inappropriately: Anti-kickback Act: providing inappropriate added value/kickback (*e.g.* doing office work for the office)."

296. In a similar document titled, *MedImmune Providing Assistance*, which was created as an E-module that ran on MedImmune's learning management system for employees to complete, there is a section titled, "Laws and Regulations", specifically on the Medicare/Medicaid anti-kickback laws. It states, "[t]he AKA prohibits offering or giving anything of value to anyone to induce the use, purchase, prescription or recommendation of products reimbursed by government healthcare payers. For example, doing general office work, such as completing or faxing in referral forms for an office may be seen as providing a valuable service for which the office would otherwise need to pay. This act could be seen as a kickback, which could qualify as a felony."

297. Despite its awareness of the anti-kickback laws, MedImmune provided such services to physicians, and pharmacies, thereby providing illegal kickback arrangements and knowingly caused Trinity, Caremark, Acro, APS and other health care providers to present false claims to Medicaid for Synagis.

L. MedImmune Violated the Assignment of Benefit Agreements with Trinity by Giving Kickbacks

298. MedImmune and Trinity entered into AOBs with defined terms and conditions, which were required for Trinity to try to obtain drug manufacturer rebates. A "rebate" is any discount, the terms of which are fixed and disclosed in writing to the buyer at the time of the

initial purchase to which the discount applies, but which is not given at the time of the sale. However, a critical term of the AOBs concerning anti-kickback statutes and regulations was violated. *Id.*, ¶174.

299. MedImmune and Trinity agreed not to violate the federal and state anti-kickback statutes, as stated in the AOBs section 3.1(d) (2006-2007 AOB). *Id.*, ¶175. This section states, "It is the intent of the parties to establish a business relationship which complies with the anti-kickback statute applicable to federal healthcare programs set forth at 42 USC 1320a-7(b)." *Id.* By a) obtaining and providing valuable infant patient leads to Trinity from NICU logbooks; b) obtaining and providing leads and/or referrals to Trinity from licensed medical professionals; and c) providing personnel assistance and PHI to Trinity to try to obtain initial Synagis prescriptions and thereafter, consent for refills, MedImmune violated terms of the AOBs and in turn violated the anti-kickback statutes and regulations. *Id.*

300. Further, as a result of the conduct, Trinity and its successor parents received rebates from MedImmune and a portion of that rebate was inevitably the result of improper Medicaid claims that Trinity presented to the State which were tainted by MedImmune's illegal conduct. *Id.*, ¶177. This additional remuneration to Trinity was another form of an illegal kickback. *Id.* Any claim presented to Medicaid as the result of a kickback is false and fraudulent. *Id.*

M. **FDA-Approved Label for Synagis**

301. On June 19, 1998, the FDA first approved MedImmune to manufacture Palivizumab with the tradename Synagis. Synagis' 2004 label states:

> INDICATIONS AND USAGE: Synagis® is indicated for the prevention of serious lower respiratory tract disease caused by

> respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Safety and efficacy were established in infants with bronchopulmonary dysplasia (BPD) and infants with a history of premature birth (= 35 weeks gestational age), and children with hemodynamically significant CHD [congenital heart disease].
>
> ***
>
> DOSAGE AND ADMINISTRATION: The recommended dose of Synagis® is 15 mg/kg of body weight. Patients, including those who develop an RSV infection, should continue to receive monthly doses throughout the RSV season. The first dose should be administered prior to commencement of the RSV season. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but it may begin earlier or persist later in certain communities.[6]

Notably, the April 2011 label for Synagis adds, "The safety and efficacy of Synagis have not been established for treatment of RSV disease" (emphasis added).

302. In December 2003, the American Academy of Pediatrics issued a policy statement (the "AAP Policy Statement") which cautioned that RSV prophylaxis should be reserved for infants born "between 32 and 35 weeks of gestation" who are "at greater risk of severe infection" and who are "younger than 6 months at the start of RSV season." The AAP Policy Statement also indicated that an RSV infection was "more likely to lead to hospitalization" when the following risk factors are present: (1) child care attendance; (2) school-aged siblings; (3) exposure to environmental air pollutants; (4) congenital abnormalities of the airways; or (5) severe neuromuscular disease.

303. The AAP Policy Statement recommended that prophylaxis "should be considered for infants between 32 and 35 weeks of gestation only if two or more of these risk factors are present." In addition, the Policy Statement stated that in most regions of the Northern

Hemisphere, "the first dose of [Synagis] should be administered at the beginning of November, and **the last dose should be administered at the beginning of March**" (emphasis added).[6]

N. Relator's Investigation

304. MedImmune has sought to expand the use of Synagis beyond the use approved by FDA, and aggressively promote the drug directly to the consumer.

305. Relator received phone inquiries from the Synagis People asking whether she would order an extra "April dose" for high-risk patients because: "viral levels are still high." She always rejected such solicitation.

306. As documented in a patient chart by Relator on March 21, 2011, Relator received VNS recertification from VNS for Synagis to cover the time period March 22, 2011 through May 20, 2011. Relator spoke to Althea from Visiting Nurse Services (Brooklyn), who stated, "the synagis company" notified VNS that RSV was still active and that many doctors were ordering doses in April. She had not heard of an official recommendation from CDC or the Health Department, and could not offer Relator a reference for this report regarding RSV season. Accordingly, Relator discontinued the recertification for the particular patient at issue, as well as her other patients who received a dose of Synagis in March. Notably, NYS Medicaid website states that the 2010-2011 RSV season's offset date was March 19, 2011. *See* https://newyork.fhsc.com/providers/cdrp_rsv_season.asp . Relator produced this document to the NYAG and USAO.

307. On March 15, 2011, Relator sent an email titled "NREVSS: suggestion/comment" to CDC, stating that a visiting nurse who asked for a new prescription for Synagis reported that

[6] The quoted language remained the same through the filing of Relator's original complaint in April 2009.

"the CDC ha[d] recommend administering synagis through the end of April," and asked CDC whether there has been a new recommendation. CDC responded that CDC does not make any recommendations regarding Synagis administration. Notably, when the visiting nurse was asked to forward a copy of the CDC recommendation, she failed to forward anything. Relator produced this document to the NYAG and USAO.

308. With the use of misappropriated PHI, MedImmune caused false statements to be made to parents and caregivers of former NICU patients in attempting to secure their consent to administration of Synagis. In one case, Trinity representatives sent written correspondence and made numerous phone calls to the parents of a patient, referred to here as "Patient No. 2," who was born full-term with a traumatic brain injury. Trinity represented to Patient No. 2's parents that Patient No. 2's treating physician had ordered Synagis and to contact Trinity. This was a false statement. Synagis is not indicated for patients with brain injuries.

309. A pediatric social worker reported to Relator that the parents of several full-term infants, who were referred for minor surgical procedures such as circumcision or hernia conditions for which Synagis is not indicated, were informed by their private doctors that they were being given monthly shots "to prevent colds." This statement is inconsistent with its FDA-approved indication for high-risk infants, but consistent with the impression created by MedImmune's marketing.

310. As Relator advised the US Attorney's Office by a letter dated October 5, 2009, AAP issued revised recommendations for the use of palivizumab on September 7, 2009. These guidelines significantly restricted the circumstances under which palivizumab is recommended for use. In response, MedImmune initiated a full-scale public relations push-back. For example,

MedImmune representatives visited doctors' offices and represented that "the AAP ha[d] issued revised guidelines for the use of Synagis that drastically curtails who will receive the drug – revisions supposed [sic] based upon cost analysis rather than new efficacy findings." Furthermore, Relator reported that MedImmune had leaked information to pediatric groups that it was threatening to sue the AAP over the 2009 Policy Statement.

O. MedImmune's Off-Label Promotion of Synagis

311. On its website, MedImmune adds further risk factors for RSV, including whether an infant (1) had low birth weight, (2) has crowded living conditions, (3) has a family history of asthma, or (4) is below the age of 12 months. Also, MedImmune's website stated: "Like the flu or common cold, RSV is a seasonal virus . . . [which] usually starts in the fall and continues into the spring."

312. MedImmune has also hired consultants to perform clinical trials. MedImmune consultants have performed studies focused primarily on high-risk infants, which have concluded that RSV treatment (*i.e.*, Synagis) should be broadened beyond the high-risk infant population. One such consultant, Dr. Caroline Breese Hall, a professor of pediatric medicine at the University of Rochester Medical School, concluded that "the rates of RSV infections requiring medical attention are high not only during infancy, but throughout the first five years of life. This factor underscores the as-yet-unmet need for an effective vaccine." Dr. Hall has reported that she has financial links to MedImmune.

313. According to a January 31, 2001 New York Times article titled "Doctors Caught in the Middle; Ad Campaign Has Parents Asking for a Costly Drug," MedImmune sponsored evening teleconferences for pediatricians. During the 45-minute calls, doctors that MedImmune

considers experts on Synagis gave advice on the treatment. For their time, Mr. Armando Anido (MedImmune's senior vice president for sales) said, MedImmune offers the pediatricians textbooks or "something of value to the doctor's practice."

314. In September 2000, MedImmune began running ads aimed at parents of all premature babies in magazines (including American Baby) and on television during shows (including "The Young and the Restless" and the "Today Show"). The print advertisement showed a photograph of a doctor putting an infant on oxygen. The main caption read, "If you knew what R.S.V. could do to your precious baby, it would take your breath away." The ad ended with: "If your baby was born early, call your pediatrician now – before it's too late."

315. MedImmune had recently hired 100 new sales representatives to visit pediatricians. They were in addition to the 500 representatives from MedImmune's marketing partner for Synagis, the Ross division of Abbot Laboratories. MedImmune also had 50 salespeople visiting doctors in hospitals.

316. According to the article, Ian R. Holzman, chief of the neonatal intensive care unit at Mount Sinai Hospital in Manhattan, said that MedImmune's sales representatives had visited him, asking him to treat all of his patients who were born at least five weeks prematurely with Synagis. "We said we are not going to do that," Dr. Holzman said. "If it were a treatment that prevented R.S.V., everyone would say, 'Use it,'" Dr. Holzman said. "But it doesn't prevent R.S.V. It makes it less serious."

317. In a YouTube video, Michael G. Marcus, MD of Maimonides Medical Center in New York addresses how to address RSV:

> The next thing we do is to immunize these patients with a new **vaccine** which prevents the serious form of the RSV infection. This

> **vaccine** is called Synagis, and is required to be given once a month throughout the high-risk time of year that is from October through March in the East Coast. In other areas of the country, the risky time of year may be slightly different but **generally we give this vaccination once a month for five to six month period** during this high-risk period to minimize the seriousness of RSV infection if the premature infants contract it.

See https://youtu.be/uw0zJe7zEQg (emphasis added). However, Synagis is not a "vaccine," and that Synagis is "generally" administered once a month for six months is inconsistent with the dosage instruction in the FDA-approved label, which contemplates the RSV season generally ending in April. Notably, Dr. Marcus has served on the speakers' bureau for MedImmune.

318. MedImmune informs patients and doctors how to get Synagis reimbursed by their insurance companies on its website. If a patient's insurance company denies coverage, MedImmune requests that the patient call the "Synagis Reimbursement Hotline at 1-877-480-8082."

319. MedImmune also provides on its website an evaluation form for "nurses" to use in evaluating patients' RSV risk. This form instructs the parents of patients to fill out the form and give it to a doctor or nurse.

320. MedImmune established, and funds, a support group named the "Thrive Network." It was established to provide information to consumers about Synagis.

321. MedImmune's website contains quotes from parents who had Synagis prescribed for their children:

- Christa's Story: "A lot of people think this RSV shot is like a flu shot, but you don't do it just once. You have to get it once a month."

- Allison's Story: "The doctors in the NICU weren't sure if my insurance would cover Synagis for Christopher. But I knew that RSV was serious enough to ask my pediatrician about it . . .."

322. MedImmune urges its customers or anyone visiting its Synagis website to "spread the word about RSV protection." Visitors to MedImmune's website are also urged to send e-cards to their friends and family, which state:

- "Don't let RSV take you by surprise."
- "Did you know that RSV is the #1 cause of hospitalization in babies under 1 year old?"

323. In a peer-reviewed article titled "Epidemiology of Respiratory Syncytial Virus in Various Regions Within North Carolina During Multiple Seasons," NC Med J, November/December 2008, Volume 69, Number 6, David A. Wilfret, MD; Brent T. Baker, MD; Elizabeth Palavecino, MD; Cassandra Moran, DO; and Daniel K. Benjamin Jr., MD, PhD concluded, "Our data suggest the RSV season in North Carolina is longer than the national average, and RSV epidemics persist during months that fall outside of those in which RSV prophylaxis is given to high-risk children. Guidelines on the administration of RSV prophylaxis should ideally be based on results of local RSV test data." Notably, the Financial Disclosure for the article states, "MedImmune, Inc., provided funding for data management …."

324. BSS-OR, an Oregon-based biotech sales specialist from 2001 to approximately 2009, covered Legacy Emanuel Hospital, in Portland. During this time, she witnessed off-label use of Synagis, including babies with Down Syndrome or cystic fibrosis receiving Synagis shots based on doctors' recommendations.

P. Off-Label Use of Synagis – Dosage (Quantity, Frequency, and Out-of-Season)

325. MedImmune caused false claims to be submitted by causing Synagis to be administered in larger quantities than specified in the FDA-approved label. MedImmune caused excess quantity of Synagis for baby's weight to be dispensed by either dispensing a larger size vial than was needed or by dispensing more vials than were needed. Despite that Synagis' label states "[t]he recommended dose of Synagis® is 15 mg/kg of body weight," Trinity routinely failed to measure the weight of the baby when administering Synagis shots and frequently ordered and/or injected more quantity of Synagis than necessary for each baby.

326. MedImmune caused false claims to be submitted by causing Synagis to be administered in more doses per season than specified in the FDA-approved label, which states: "Patients, including those who develop an RSV infection, should continue to receive monthly doses throughout the RSV season. The first dose should be administered prior to commencement of the RSV season. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but it may begin earlier or persist later in certain communities."

327. In September of 2008, a New York Medicaid Update was issued by the New York State Department of Health ("NYSDOH") concerning "Synagis Medicaid Coverage for Children at Risk for Respiratory Syncytial Virus Infection." It stated that the number of monthly doses of Synagis was five throughout the RSV season, typically beginning in November in New York.

328. Also, according to the 2014 updated guidance issued by the American Academy of Pediatrics, (i) children who qualify for Synagis prophylaxis for the entire RSV season should receive monthly injections only during the five months following the onset of RSV season in

their region, and (ii) benefits for the use of Synagis to prevent complications of RSV infection in defined high risk patients are for a maximum of five doses one month apart. There should only be five doses injected into an infant in a typical RSV season.

329. The National Respiratory and Enteric Viruses Surveillance System (NREVSS) coordinates the collection of weekly virology data for RSV. RSV surveillance of the onset/offset dates is conducted by Surveillance Data, Inc. (SDI) with support from MedImmune.[7] The table below is a summary of Region 2 (New York) RSV season onset and offset, as reported by U.S. Department of Health and Human Services (HHS) Region 2 - National Respiratory and Enteric Virus Surveillance System.

Region 2 States: New York and New Jersey		
Season	**Onset Week Ending**	**Offset Week Ending**
2007-2008	10/20	2/2
2008-2009	11/15	2/28
2009-2010	11/7	Not Reported
2010-2011	11/13	3/19
2011-2012	11/12	3/17
2012-2013	11/3	3/16
2013-2014	11/16	1/25

330. As seen in the table above, the offset date for the RSV season was February 2,

[7] *See, e.g.*, https://www.cdc.gov/mmwR/PDF/wk/mm5750.pdf.

2008; February 28, 2009; March 13, 2010[8]; and March 19, 2011, for the respective seasons. In other words, each and every one of these RSV seasons ended before April.

331. In Exhibits C(1) and C(2) to the State Cmpt., there is payment data for more than 600 babies who were on lists provided by MedImmune found in Trinity's documents. Not only were those kickbacks in the form of "leads" converted to actual Medicaid payments, those infants were also targeted for extra doses, beyond the documented RSV season. In these exhibits collectively, there are 267 occurrences of payments made after the RSV season had clearly ended in the New York region according to a database that MedImmune supported. Also, 251 out of 609 babies (41.2%) received 6 or more doses of Synagis. Furthermore, there are 96 instances of 7th doses; 19 instances of 8th doses; 1 instance of 9th dose; and 1 instance of 10th dose.

332. In September of 2008, a New York Medicaid Update was issued by NYSDOH concerning "Synagis Medicaid Coverage for Children at Risk for Respiratory Syncytial Virus Infection." State Cmpt., ¶169. The Update stated that the number of monthly doses of Synagis was five throughout the RSV season, typically beginning in November in New York. MedImmune employees and supervisors, upon becoming aware of this update, commented in an email thread dated October 16, 2008. *Id.* In this email, CMM 1 referenced the update to Medi Manager 1, and attached a link to the Medicaid Update. *Id.* CMM 1 stated, "Did you already see this or was this what you were referring to this morning? Yikes. Anyway I am banking on the slow movement of the Medicaid employees to get through the season..." *Id.* Medi Manager 1 responded to CMM 1 in an email, also dated October 16, 2008. He confirmed what CMM 1 had stated, "Yes… the policy is exactly what I was referring to this AM… Note, they mention starts

[8] Because the RSV offset date for the 2009-2010 season was not reported in the table above, for that season, the offset date for Northeast as determined by a National Surveillance System was used instead. *See*

of season in November with (5) doses. Sounds very commercial, does it not? No mention of April. The statement is a departure from last season." *Id.*

333. According to RSVAlert®,[9] a US surveillance system, which collects and characterizes RSV test data at national, regional, state and local levels, following was the RSV season in the West Coast. Based on this information, even in West Coast where the RSV season typically starts later than East Coast, the RSV season ended in late March or early April with the exception of the 2011-2012 RSV season.

Season	West
2007-2008	
Onset	December 8, 2007
Offset	March 29, 2008
Duration, weeks	17
2008-2009	
Onset	December 6, 2008
Offset	March 28, 2009
Duration, weeks	17
2009-2010	
Onset	December 26, 2009
Offset	April 3, 2010
Duration, weeks	15
2010-2011	
Onset	December 11, 2010
Offset	April 2, 2011
Duration, weeks	17
2011-2012	
Onset	December 31, 2011
Offset	April 28, 2012
Duration, weeks	18

334. Similarly, BSS-CA3 reported that MedImmune also engaged in "pushing an extra dose" of Synagis outside of the RSV season. BSS-CA3 was encouraged to recommend to the

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4025589/.

[9] RSVAlert is funded under a contract with MedImmune and managed by IMS Health. This study was sponsored by MedImmune.

pediatricians that they consider prescribing an "extra dose" to the babies; they treated after the RSV season had already ended.

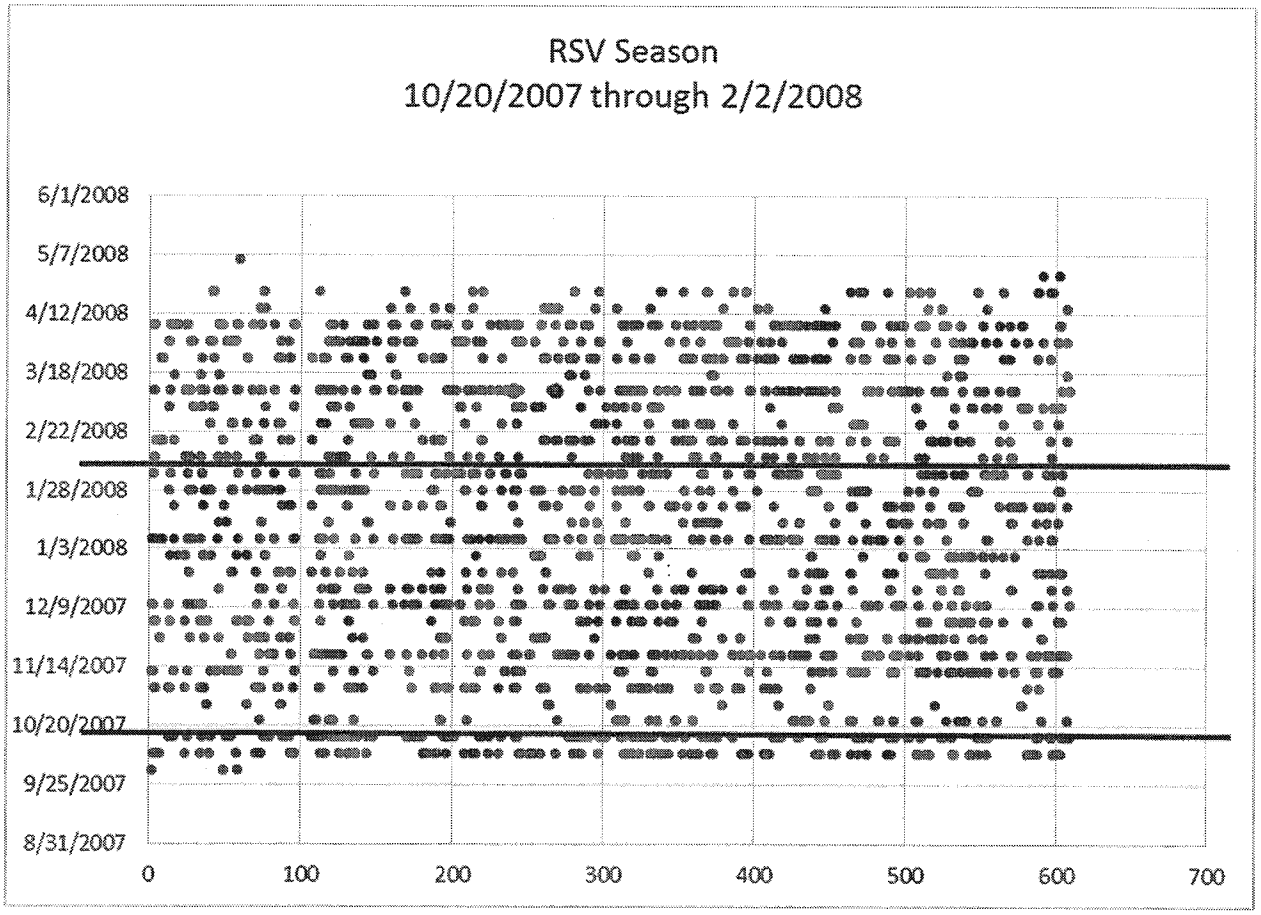
335. BSS-CA3 explained that this activity was directed from the "top down." BSS-CA3 noted that Acerboni recommended at sales meetings that the biotech sales specialists point the doctors to a particular website that detailed the presence of RSV, even after the RSV season ended. BSS-CA3 and the other sales representatives were encouraged by Acerboni to tell the doctors that "RSV was still around" and that they might want to consider another dose of Synagis, even though the RSV season had ended. So, while the RSV season might have been five or six months in Southern California, Acerboni encouraged his sales team to recommend a sixth or seventh dose of the drug based on the website data.

336. BSS-CA3 further explained that representatives were "not allowed" to give the doctors any handouts on the topic of extra doses, but were allowed and encouraged to name the website that was used to demonstrate that there were still cases of RSV in the area.

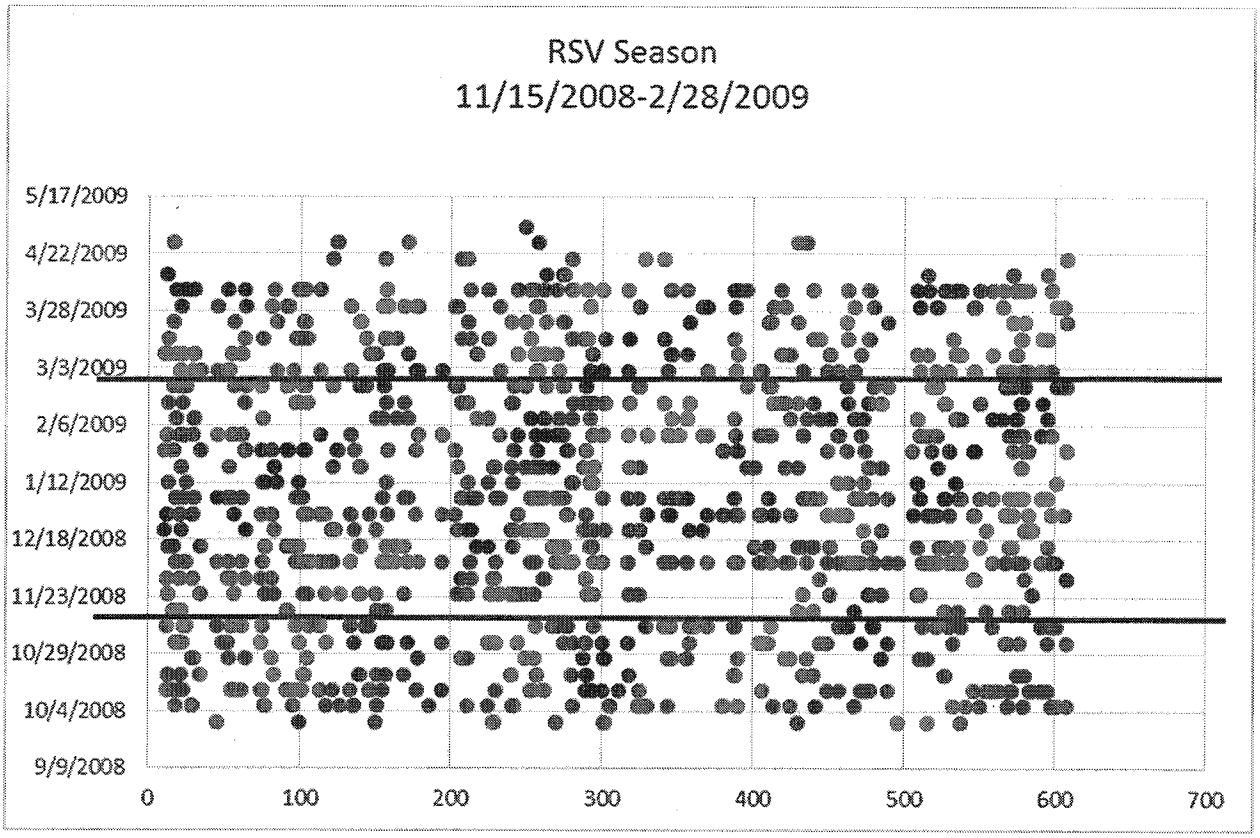
337. MedImmune assists in the compilation of data disseminated to track instances of RSV, which fixes the start and end date annually of RSV season. MedImmune caused false claims to be submitted by causing Synagis to be administered outside of the time period of RSV season according to its data. MedImmune also provided PHI to promote Synagis injections for the identified babies for two RSV seasons in a row. In Exhibit C(1), there are 14 instances of season 2 administration of synagis. In Exhibit C(2), there are 68 instances of season 2 administration of synagis.

338. MedImmune caused false claims to be submitted by causing Synagis to be administered outside the RSV season as suggested in the examples below. These scatter grams

were derived from the data in the Exhibits C(1) and C(2). These charts reflect the time frame for the actual RSV seasons from reported data and are from a database that MedImmune supports. Blue dots indicate Medicaid payments received by Trinity, and the red lines indicate the onset and offset dates of the RSV season. The numbers on the X-axis represent the numbers ascribed to more than 600 babies for identification in lieu of names. The Y-axis represents the date of Medicaid payment received by Trinity, as opposed to the actual date of Synagis injections.[10]



[10] With the exception of the RSV offset date for the 2009-2010 season, the historical onset and offset dates for RSV seasons, as reported by U.S. Department of Health and Human Services (HHS) Region 2 – National Respiratory and Enteric Virus Surveillance System, are found on the website for NYS Medicaid Pharmacy Prior Authorization Programs. (https://newyork.fhsc.com/providers/cdrp_rsv_season.asp)



Q. <u>The Claims Asserted Herein Relate Back to the Original Complaint</u>

339. The claims asserted herein are timely because they relate back under 15(c)(1)(B), FED. R. CIV. P., to the initial *qui tam* complaint, filed under seal on April 20, 2009 against MedImmune and the settled Pharmacy Defendants. The initial complaint alleged that MedImmune and the settled Pharmacy Defendants violated the Federal False Claims Act and the false claims acts of 19 States, based on the misappropriation of HIPAA-protected PHI from the NICU at Bellevue Hospital and the off-label promotion of Synagis, which was used to increase claims for Synagis paid for by Federal and State Medicaid programs. The claims asserted herein relate back because they are based on the same set of core facts arsing from the misappropriation of PHI from hospital NICUs to increase Synagis claims. The State claims against MedImmune are likewise timely because they relate back to the initial complaint under the applicable State

Statutes.

340. Alternatively, the claims are timely under the FCA because they were brought less than three years after the date when the US official responsible to act in the circumstances knew or reasonably should have known facts material to the claims, and not more than 10 years after the alleged FCA violation, 31 U.S.C. §3731(b)(2). Similarly, the State claims against MedImmune are timely because the limitations periods for the applicable State Statutes, which are substantially the same as the 10-year period provided under 31 U.S.C. §3731(b)(2).

COUNT ONE

(Violation of Federal False Claims Act)
(31 U.S.C. § 3729(a))

341. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

342. This count sets forth claims for treble damages and forfeitures under the federal False Claims Act, 31 U.S.C. §§ 3729-3732, as amended.

343. Defendants' nationwide practices of (i) accessing patient logs at hospital NICUs/PICUs as well as physicians' offices to provide specialty pharmacies with PHI, and (ii) providing other benefits to physicians as described above, have resulted in MedImmune providing kickbacks to pharmacies and physicians who, in turn, improperly seek reimbursement for Synagis from Medicaid.

344. Defendants have knowingly violated:

a. 31 U.S.C. § 3729(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent

claim for payment or approval;

b. 31 U.S.C. § 3729(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; and

c. 31 U.S.C. § 3729(a)(3) by conspiring to defraud the Government by getting a false or fraudulent claim allowed or paid.

345. The United States, unaware of the falsity of the claims, approved, paid, and participated in payments made by the United States for claims that otherwise would not have been allowed.

346. By reason of these payments and approvals, the United States has been damaged in an amount yet to be determined.

COUNT TWO

(Violation of New York False Claims Act)
(N.Y. Fin. Law §§ 189, *et seq.*)

347. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

348. The NYAG has intervened to prosecute claims against MedImmune as to the New York cause of action and to recover damages on behalf of New York State. Relator sets forth below to preserve all rights and claims as to New York, should the NYAG choose to discontinue its prosecution.

349. As a result of MedImmune's kickbacks and offers of kickbacks to induce Trinity and Caremark to purchase, order, or recommend Synagis in violation of New York Social Services Law § 366-f, 18 N.Y.C.R.R. § 515.2(b), the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Medicaid program, MedImmune knowingly caused Trinity to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of New York, in violation of N.Y. Fin. Law §§ 189(1)(b), *et seq.*

350. The false records, statements, and/or omissions were Trinity's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable New York and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations and the laws, rules, and regulations of the New York State Medicaid program, including its Medicaid updates and provider manuals.

351. By virtue of the acts described above, MedImmune "knowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" to the State of New York or a political subdivision, in violation of N.Y. Fin. Law § 189(1)(a).

352. By virtue of the acts described above, MedImmune "knowingly ma[de], us[ed], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" for payment to the State of New York or a political subdivision, in violation of N.Y. Fin. Law § 189(1)(b).

353. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the New York False Claims Act.

354. The New York State Government, unaware of the falsity of the records, statements, and/or claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

355. By reason of MedImmune's acts, the State of New York has been damaged in a substantial amount to be determined at trial.

356. Pursuant to N.Y. Fin. Law § 189(1)(h), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false and fraudulent claim, record or statement made, used, presented or caused to be made, used, or presented by MedImmune.

COUNT THREE

(Violation of the California False Claims Act)
(Cal. Gov't Code § 12651(a)(1)-(3))

357. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

358. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark and APS to purchase, order, or recommend Synagis in violation of California Business and Professionals Code § 650, California Welfare and Institutions Code § 14107.2, California Health and Safety Code § 445, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the California Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of California, in violation of Cal. Gov't Code §§ 12650, *et seq.*

359. The false records, statements, and/or omissions were Caremark' false certifications, representations, and/or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the California State Medicaid program.

360. By virtue of the acts described above, MedImmune "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" to the State of California or a political subdivision, in violation of Cal. Gov't Code § 12651(a)(1).

361. By virtue of the acts described above, MedImmune "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" for payment presented to the State of California or a political subdivision, in violation of Cal. Gov't Code § 12651(a)(2).

362. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the California False Claims Act.

363. The California State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

364. By reason of MedImmune's acts, the State of California has been damaged in a substantial amount to be determined at trial.

365. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every

fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT FOUR

(Violation of Delaware False Claims and Reporting Act)
(Del. Code Ann. §§ 1201, *et seq.*)

366. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

367. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of 31 Del. Code Ann. § 1005, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Delaware Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Delaware, in violation of Del. Code Ann. §§ 1201, *et seq.*

368. The false records, statements, and/or omissions were Caremark' false certifications, representations, or omissions that the services were provided in compliance with all applicable Delaware and Federal laws and regulations, including but not limited to, Delaware and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Delaware Medicaid program.

369. By virtue of the acts described above, MedImmune "[k]nowingly present[ed], or cause[d] to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval," in violation of Del. Code Ann. § 1201(a)(1).

370. By virtue of the acts described above, MedImmune "[k]nowingly ma[de], use[d], or cause[d] to be made or used, directly or indirectly, a false record or statement to get a false or

fraudulent claim paid or approved," in violation of Del. Code Ann. § 1201(a)(2).

371. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Delaware False Claims and Reporting Act.

372. The Delaware State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

373. By reason of MedImmune's acts, the State of Delaware has been damaged in a substantial amount to be determined at trial.

374. Pursuant to Del. Code Ann. § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT FIVE

(Violation of Florida False Claims Act)
(Fla. Stat. §§ 68.081, *et seq.*)

375. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

376. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark and Trinity to purchase, order, or recommend Synagis in violation of Fla. Stat. § 456.054, Fla. Stat. § 409.920, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Florida and Federal Medicaid programs, MedImmune knowingly caused Caremark and Trinity to make false records, statements, and/or omissions that were material to

false or fraudulent claims for payment presented to the State of Florida, in violation of Fla. Stat. § 68.081, *et seq.*

377. The false records, statements, and/or omissions were Caremark's and Trinity's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable Florida and Federal laws, including but not limited to, Florida and Federal anti-kickback statutes and regulations, and all Florida and Federal laws, rules, regulations, and statements of policy applicable to the Medicaid program, including the Medicaid Provider Handbooks issued by the Florida Agency for Health Care Administration.

378. By virtue of the acts described above, MedImmune "[k]nowingly present[ed] or cause[d] to be presented to an officer or employee of an agency a false or fraudulent claim for payment or approval," in violation of Fla. Stat. § 68082(2)(a).

379. By virtue of the acts described above, MedImmune "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency," in violation of Fla. Stat. § 68082(2)(b).

380. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Florida False Claims Act.

381. The Florida State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

382. By reason of MedImmune's acts, the State of Florida has been damaged in a substantial amount to be determined at trial.

383. Pursuant to Fla. Stat. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT SIX

(Violation of Georgia False Medicaid Claims Act)
(Ga. Code Ann. §§ 49-4-168.1, *et seq.*)

384. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

385. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of the Federal Anti-Kickback Statute and the laws, rules, and regulations of the Georgia Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Georgia, in violation of Ga. Code Ann. §§ 49-4-168.1, *et seq.*

386. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omission that the services were provided in compliance with all applicable Georgia and Federal laws and regulations, including but not limited to, Georgia and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Georgia Medicaid program, including Georgia's Policies and Procedures for Medicaid/PeachCare for Kids Manual.

387. By virtue of the acts described above, MedImmune "[k]nowingly present[ed] or cause[d] to be presented to the Georgia Medicaid program a false or fraudulent claim for

payment or approval" in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

388. By virtue of the acts described above, MedImmune "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" to the Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

389. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Georgia False Medicaid Claims Act.

390. The Georgia State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

391. By reason of MedImmune's acts, the State of Georgia has been damaged in a substantial amount to be determined at trial.

392. Pursuant to Ga. Code Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT SEVEN

(Violation of Illinois False Claims Act)
(740 Ill. Comp. Stat. §§ 175/1, *et seq.*)

393. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

394. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of 720 ILCS 5/33E-7, the

Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Illinois Medicaid program, MedImmune knowingly caused CAREMARK to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Illinois, in violation of 740 ILCS 175/1, *et seq.*

395. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable Illinois, Federal, and Illinois Department of Healthcare and Family Services laws, regulations, rules, requirements, policies, and procedures, including but not limited to, Illinois and Federal anti-kickback statues and regulations, and the laws, rules, and regulations of the State of Illinois Medicaid program, including program provider handbooks, policies, and requirements.

396. By virtue of the acts described above, MedImmune "[k]nowingly present[ed], or cause[d] to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval," in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

397. By virtue of the acts described above, MedImmune "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State," in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

398. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Illinois False Claims Act.

399. The Illinois State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged

herein.

400. By reason of MedImmune's acts, the State of Illinois has been damaged in a substantial amount to be determined at trial.

401. Pursuant to Ill. Comp. Stat. 740 § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT EIGHT

(Violation of Indiana False Claims and Whistleblower Protection Act)
(Ind. Code §§ 5-11-5.5-1, *et seq.*)

402. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

403. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of Ind. Code § 12-15-24-2, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Indiana Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Indiana, in violation of Ind. Code §§ 5-11-5.5-1, *et seq.*

404. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable Indiana and Federal laws and regulations, including but not limited to, Indiana and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Indiana State Medicaid program or Children's Health Insurance Program.

405. By virtue of the acts described above, MedImmune knowingly presented, or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

406. By virtue of the acts described above, MedImmune knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

407. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Indiana False Claims and Whistleblower Protection Act.

408. The Indiana State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

409. By reason of MedImmune's acts, the State of Indiana has been damaged in a substantial amount to be determined at trial.

410. Pursuant to Ind. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus at least $5,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT NINE

(Violation of Massachusetts False Claims Law)
(Mass. Gen. Laws ch. 12, §§ 5A, *et seq.*)

411. Relator repeats and incorporates by reference the allegations contained in the

preceding paragraphs of this Complaint as though fully set forth herein.

412. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of Mass. Gen. Laws ch. 118E § 41, Mass. Gen. Laws ch. 175H § 3, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Massachusetts Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Massachusetts, in violation of Mass. Gen. Laws ch. 12, §§ 5A, *et seq*.

413. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable Massachusetts and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Massachusetts Medicaid program.

414. By virtue of the acts described above, MedImmune "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval," in violation of Mass. Gen. Laws ch. 12, § 5B(1).

415. By virtue of the acts described above, MedImmune "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof," in violation of Mass. Gen. Laws ch. 12, § 5B(2).

416. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Massachusetts False Claims Law.

417. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

418. By reason of MedImmune's acts, the Commonwealth of Massachusetts has been damaged in a substantial amount to be determined at trial.

419. Pursuant to Mass. Gen. Laws ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT TEN

(Violation of Michigan Medicaid False Claims Act)
(Mich. Comp. Laws §§ 400.601, *et seq.*)

420. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

421. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of Mich. Comp. Laws § 400.604, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Michigan Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Michigan, in violation of Mich. Comp. Laws §§ 400.601, *et seq.*

422. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance

with all applicable Michigan and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Michigan State Medicaid program.

423. By virtue of the acts described above, MedImmune knowingly presented, or caused to be presented, false or fraudulent claims to the State of Michigan for payment or approval.

424. By virtue of the acts described above, MedImmune knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

425. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Michigan Medicaid False Claims Act.

426. The Michigan State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

427. By reason of MedImmune's acts, the State of Michigan has been damaged in a substantial amount to be determined at trial.

428. Pursuant to Mich. Comp. Laws § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud plus triple the amount of damages suffered by the state as a result of MedImmune's conduct.

COUNT ELEVEN

(Violation of Montana False Claims Act)
(Mont. Code Ann. §§ 17-8-401, *et seq.*)

429. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

430. As a result of MedImmune's kickbacks and offers of kickbacks to induce APS and Caremark to purchase, order, or recommend Synagis in violation of Mont. Code Ann. § 45-6-313, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Montana Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Montana, in violation of Mont. Code Ann. §§ 17-8-401, *et seq.*

431. The false records, statements, or omissions were Caremark's false certifications, representations, or omissions that the services were provided in compliance with all applicable Montana and Federal laws and regulations, including but not limited to, Montana and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Montana State Medicaid program.

432. By virtue of the acts described above, MedImmune knowingly presented, or caused to be presented, false or fraudulent claims to the State of Montana for payment or approval.

433. By virtue of the acts described above, MedImmune knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

434. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Montana False Claims Act.

435. The Montana State Government, unaware of the falsity of the records, statements,

and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

436. By reason of MedImmune's acts, the State of Montana has been damaged in a substantial amount to be determined at trial.

437. Pursuant to Mont. Code Ann. § 17-8-403, the State of Montana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT TWELVE

(Violation of Nevada False Claims Act)
(Nev. Rev. Stat. §§ 357.010, *et seq.*)

438. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

439. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of Nev. Rev. Stat. § 422.560, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Nevada Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Nevada, in violation of Nev. Rev. Stat. §§ 357.010, *et seq.*

440. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Nevada State Medicaid program.

441. By virtue of the acts described above, MedImmune "[k]nowingly present[ed] or cause[d] to be presented a false claim for payment or approval," in violation of Nev. Rev. Stat. § 357.040(1)(a).

442. By virtue of the acts described above, MedImmune "[k]nowingly ma[de] or use[d], or cause[d] to be made or used, a false record or statement to obtain approval of a false claim," in violation of Nev. Rev. Stat. § 357.040(1)(b).

443. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Nevada False Claims Act.

444. The Nevada State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

445. By reason of MedImmune's acts, the State of Nevada has been damaged in a substantial amount to be determined at trial.

446. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or

presented by MedImmune.

COUNT THIRTEEN

(Violation of New Jersey False Claims Act)
(N.J. Stat. Ann. §§ 2A:32C-1, *et seq.*)

447. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

448. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark and Trinity to purchase, order, or recommend Synagis in violation of N.J. Stat. Ann. § 30:4D-17, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the New Jersey Medicaid program, MedImmune knowingly caused Caremark and Trinity to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of New Jersey, in violation of N.J. Stat. Ann. §§ 2A:32C-1, *et seq.*

449. The false records, statements, and/or omissions were Caremark's and Trinity's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the New Jersey State Medicaid program.

450. By virtue of the acts described above, MedImmune knowingly presented, or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

451. By virtue of the acts described above, MedImmune knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

452. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the New Jersey False Claims Act.

453. The New Jersey State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

454. By reason of MedImmune's acts, the State of New Jersey has been damaged in a substantial amount to be determined at trial.

455. Pursuant to N.J. Stat. Ann. § 1201(a), the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT FOURTEEN

(Violation of New Mexico Medicaid False Claims Act)
(N.M. Stat. Ann. §§ 27-14-1, *et seq.*)

456. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

457. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of N.M. Stat. Ann. § 30-44-7, N.M. Stat. Ann. § 30-41-1, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the New Mexico Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of New Mexico, in violation of N.M. Stat. Ann. §§ 27-14-1, *et*

seq.

458. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the New Mexico State Medicaid program.

459. By virtue of the acts described above, MedImmune "present[ed], or cause[d] to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent," in violation of N.M. Stat. Ann. § 27-14-4(A).

460. By virtue of the acts described above, MedImmune "ma[de], use[d] or cause[d] to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false," in violation of N.M. Stat. Ann. § 27-14-4(C).

461. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the New Mexico False Claims Act.

462. The New Mexico State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

463. By reason of MedImmune's acts, the State of New Mexico has been damaged in a substantial amount to be determined at trial.

464. Pursuant to N.M. Stat. Ann. § 27-14-4, the State of New Mexico is entitled to

three times the amount of actual damages plus the maximum penalty that may be applicable for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT FIFTEEN

(Violation of Oklahoma Medicaid False Claims Act)
(63 Okla. Stat. Ann. §§ 5053, *et seq.*)

465. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

466. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of 56 Okla. Stat. Ann. § 1005, 63 Okla. Stat. Ann. § 1-742, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Oklahoma Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Oklahoma, in violation of 63 Okla. Stat. Ann. §§ 5053, *et seq.*

467. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Oklahoma State Medicaid program.

468. By virtue of the acts described above, MedImmune knowingly presented, or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

469. By virtue of the acts described above, MedImmune knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

470. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Oklahoma False Claims Act.

471. The Oklahoma State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

472. By reason of MedImmune's acts, the State of Oklahoma has been damaged in a substantial amount to be determined at trial.

473. Pursuant to 63 Okla. Stat. Ann. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT SIXTEEN

(Violation of the State False Claims Act (Rhode Island))
(R.I. Gen. Laws §§ 9-1.1-1, *et seq.*)

474. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

475. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of R.I. Gen. Laws § 40-8.2-3, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Rhode Island

Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Rhode Island, in violation of R.I. Gen. Laws §§ 9-1.1-1, *et seq.*

476. The false records, statements, or omissions were Caremark's false certifications, representations, or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, anti-kickback statutes and regulations, and the laws, rules, and regulations of the Rhode Island Medicaid program.

477. By virtue of the acts described above, MedImmune knowingly presented, or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

478. By virtue of the acts described above, MedImmune knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

479. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the State False Claims Act.

480. The Rhode Island State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

481. By reason of MedImmune's acts, the State of Rhode Island has been damaged in a substantial amount to be determined at trial.

482. Pursuant to R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island is entitled to three

times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT SEVENTEEN

(Violation of Tennessee Medicaid False Claims Act)
(Tenn. Code §§ 71-5-181, *et seq.*)

483. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

484. As a result of MedImmune's kickbacks and offers of kickbacks to induce Acro and Caremark to purchase, order, or recommend Synagis in violation of the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Tennessee Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Tennessee, in violation of Tenn. Code §§ 71-5-181, *et seq.*

485. The false records, statements, or omissions were Caremark's false certifications, representations, or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Tennessee State Medicaid program.

486. By virtue of the acts described above, MedImmune "[p]resent[ed], or cause[d] to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent," in violation of Tenn. Code § 71-5-182(a)(1)(A).

487. By virtue of the acts described above, MedImmune "ma[de], use[d], or cause[d] to

be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false," in violation of Tenn. Code § 71-5-182(a)(1)(B).

488. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Tennessee Medicaid False Claims Act.

489. The Tennessee State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

490. By reason of MedImmune's acts, the State of Tennessee has been damaged in a substantial amount to be determined at trial.

491. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT EIGHTEEN

(Violation of Texas Medicaid Fraud Prevention Act)
(Tex. Hum. Res. Code §§ 36.001, *et seq.*)

492. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

493. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of 1 TAC § 371.1669, Tex. Hum. Res. Code § 32.039, the Federal Anti-Kickback Statute, and the laws, rules, and

regulations of the Texas Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Texas, in violation of Tex. Hum. Res. Code §§ 36.001, *et seq.*

494. The false records, statements, or omissions were Caremark's false certifications, representations, or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Texas State Medicaid program.

495. By virtue of the acts described above, MedImmune knowingly presented, or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval, in violation of Tex. Hum. Res. Code § 36.002(6).

496. By virtue of the acts described above, MedImmune knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims, in violation of Tex. Hum. Res. Code § 36.002.

497. Moreover, in creating and implementing the kickback scheme described above, Defendants conspired to commit violations of the Texas Medicaid Fraud Prevention Act.

498. The Texas State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

499. By reason of MedImmune's acts, the State of Texas has been damaged in a substantial amount to be determined at trial.

500. Pursuant to Tex. Hum. Res. Code § 36.052, the State of Texas is entitled to three times the amount of actual damages plus the maximum penalty of $15,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT NINETEEN

(Violation of Virginia Fraud Against Taxpayers Act)
(Va. Code Ann. §§ 8.01-216.1, *et seq.*)

501. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

502. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of Va. Code Ann. § 32.1-315, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Virginia Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of Virginia, in violation of Va. Code Ann. §§ 8.01-216.1, *et seq.*

503. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Virginia State Medicaid program.

504. By virtue of the acts described above, MedImmune "[k]nowingly present[ed], or cause[d] to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval," in violation of Va. Code Ann. § 8.01-216.3(A)(1).

505. By virtue of the acts described above, MedImmune "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved," in violation of Va. Code Ann. § 8.01-216.3(A)(2).

506. The Virginia Commonwealth Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

507. By reason of MedImmune's acts, the State of Virginia has been damaged in a substantial amount to be determined at trial.

508. Pursuant to Va. Code Ann. § 801-216.3(A), the State of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

COUNT TWENTY

(Violation of Wisconsin False Claims for Medical Assistance Law)
(Wis. Stat. § 20.931)

509. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

510. As a result of MedImmune's kickbacks and offers of kickbacks to induce Caremark to purchase, order, or recommend Synagis in violation of Wis. Stat. § 946.91, the Federal Anti-Kickback Statute, and the laws, rules, and regulations of the Wisconsin Medicaid program, MedImmune knowingly caused Caremark to make false records, statements, and/or omissions that were material to false or fraudulent claims for payment presented to the State of

Wisconsin, in violation of Wis. Stat. § 20.931, *et seq.*

511. The false records, statements, and/or omissions were Caremark's false certifications, representations, and/or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules, and regulations of the Wisconsin State Medicaid program.

512. By virtue of the acts described above, MedImmune knowingly presented, or caused to be presented, false, or fraudulent claims to the Wisconsin State Government for payment or approval.

513. By virtue of the acts described above, MedImmune knowingly made, used, or caused to be made or used, false records, and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

514. The Wisconsin State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by MedImmune, paid claims that would not have been paid but for the acts and/or conduct of MedImmune as alleged herein.

515. By reason of MedImmune's acts, the State of Wisconsin has been damaged in a substantial amount to be determined at trial.

516. Pursuant to Wis. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by MedImmune.

PRAYER FOR RELIEF

WHEREFORE, Relator requests, on behalf of the United States and the named States, that judgment be entered against Defendant, ordering that:

WITH RESPECT TO THE FEDERAL CLAIMS:

A. Defendants pay an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty against Defendants of not less than $5,000, and not more than $11,000, for each violation of 31 U.S.C. § 3729;

B. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

C. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*;

D. Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d); and

E. The United States and Relator be granted all such other relief as the Court deems just and proper.

WITH RESPECT TO THE STATE CLAIMS:

A. Relator and each named State Plaintiff be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each State as a result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendants within each States, all as provided by:

Cal. Gov't Code §§ 12651;
Fla. State §§ 68.082;
N.J. Stat. Ann. §§ 2A:32C-3;
N.Y. Fin. Law §§ 189.1(g);

B. Relator and Plaintiff State of Texas be awarded statutory damages in an amount equal to two times the amount of actual damages that Texas has sustained as a result of the Defendants' actions, as well as the maximum statutory civil penalty for each violation of Tex. Hum. Res. Code § 36.052;

C. Relator be awarded her share of any judgment to the maximum amount provided pursuant to:

Cal. Gov't Code § 12652(g);
Fla. State § 68.085;
N.J. Stat. Ann. § 2A:32C-7;
N.Y. Fin. Law § 190.6;

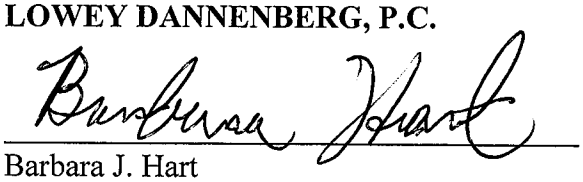
D. Relator be awarded all costs and expenses associated with each of the pendent State claims, plus attorneys' fees, as provided pursuant to:

Cal. Gov't Code § 12652(g)(8);
Fla. State § 68.086;
N.J. Stat. Ann. § 2A:32C-7;
N.Y. Fin. Law § 190.7;

E. Relator and the State Plaintiffs be awarded such other and further relief as the Court may deem to be just and proper.

Dated: August 24, 2017
White Plains, New York

LOWEY DANNENBERG, P.C.

By: 

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